

ATTACHMENT 1

Legal Authority

Excerpts From The Public Health Services Act

PART C -- SPECIFIC PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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Subpart 1 -- National Cancer Institute

PURPOSE OF INSTITUTE

SEC. 410. [285] The general purpose of the National Cancer Institute (hereafter in this subpart referred to as the "Institute") is the conduct and support of research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients.

NATIONAL CANCER PROGRAM

SEC. 411. [285a] The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute.

CANCER CONTROL PROGRAMS

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SEC. 412. [285a-1] The Director of the Institute shall establish and support demonstration, education, and other programs for the detection, diagnosis, prevention, and treatment of cancer and for rehabilitation and counseling respecting cancer. Programs established and supported under this section shall include--

(1) locally initiated education and demonstration programs (and regional networks of such programs) to transmit research results and to disseminate information respecting--

(A) the detection, diagnosis, prevention, and treatment of cancer,

(B) the continuing care of cancer patients and the families of cancer patients, and

(C) rehabilitation and counseling respecting cancer, to physicians and other health professionals who provide care to individuals who have cancer;

(2) the demonstration of and the education of students of the health professions and health professionals in--

(A) effective methods for the prevention and early detection of cancer and the identification of individuals with a high risk of developing cancer, and

(B) improved methods of patient referral to appropriate centers for early diagnosis and treatment of cancer; and

(3) the demonstration of new methods for the dissemination of information to the general public concerning the prevention, early detection, diagnosis, and treatment and control of cancer and information concerning unapproved and ineffective methods, drugs, and devices for the diagnosis, prevention, treatment, and control of cancer.

ATTACHMENT 2a

Household Screener

HINTS II

HEALTH INFORMATION NATIONAL TRENDS SURVEY

MAIN STUDY INTERVIEW INSTRUMENT (ENGLISH)

June 2004

OMB Version

NATIONAL CANCER INSTITUTE (NCI)

The Privacy Act requires us to tell you that we are authorized to collect this information by Section 285a, 42 USC. You do not have to provide the information requested. However, the information you provide will help the National Cancer Institute's ongoing efforts to promote good health and prevent disease. There are no penalties should you choose not to participate in this study.

The information we collect in this study is in accordance with the clearance requirements of the paperwork Reduction Act of 1995. We may not conduct or sponsor, and you are not required to respond to, a collection of information unless it displays a valid control number from the Office of Management and Budget in the Federal Government. We estimate that it will take you between 20 and 30 minutes to answer our questions in this interview. This includes the time it takes to hear the instructions, gather the necessary facts, and complete the interview. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx)

HOUSEHOLD ENUMERATION (HE)

HE-0. [PHONE NUMBER]

- USE AUTODIALER 1
- BYPASS AUTODIALER 2

[SINTRO_1] Hello, the National Cancer Institute, a Federal government agency, is conducting a nationwide survey to understand concerns people like you may have about cancer.

HE-1. Are you a member of this household and at least 18 years old?

- YES 1 (HE-3)
- NO 2
- BUSINESS ADDRESS 3 (END STATEMENT)

HE-2. May I speak to a member of this household who is at least 18 years old?

- AVAILABLE 1 (SINTRO_1)
- NOT AVAILABLE 2 (MAKE APPOINTMENT)
- THERE ARE NONE 3 (END STATEMENT)

HE-3. Is this phone number used for...

- home use, 1
- home and business use, or 2
- business use only? 3 (END STATEMENT)
- GO TO RESULT GT (RESULT)

[HE-4 INTRO] The main purpose of this study is to learn what people know about cancer and how they get their information about it. You may have received a letter from the National Cancer Institute introducing this study. I have some questions to see whether you or any member of your household may be eligible to participate in this survey.

HE-4. Including yourself, how many people aged 18 or older currently live in this household?

[IF NEEDED: "Include people who usually stay in this household, but are temporarily away on business, vacation, or in the hospital. Do not include persons who are away on full-time active military duty with the armed forces, students living away from home in their own apartment, or any other family member who may be in a nursing home or other institution."]

 |_|_|
OF ADULT HH MEMBERS

BOX HE-1

IF THERE ARE NO ADULT HH MEMBERS, GO TO END STATEMENT.
 IF ONLY 1 ADULT IN HH, GO TO HE-9.
 OTHERWISE, RUN RESPONDENT SELECTION ALGORITHM.
 IF RESPONDENT WAS SAMPLED, GO TO HE-9.
 IF 2 ADULTS IN HH, GO TO HE-9.
 IF 3 ADULTS IN HH, GO TO HE-5.
 OTHERWISE IF MORE THAN 3 ADULTS IN HH AND RESPONDENT WAS NOT SAMPLED, GO TO HE-6.

HE-5. The computer has randomly determined that one of the adults in the household other than yourself should be selected for the rest of the interview. To help us select this person, please tell me which of these two adults is the (youngest/oldest)?

[PROBE FOR GENDER (IF NOT OBVIOUS) AND AGE OF HH MEMBER SELECTED.]

NAME: _____

GENDER: MALE 1 AND AGE:
 FEMALE..... 2

DK..... (HE-8)
 RF..... (END STATEMENT)

GO TO HE-10.

HE-6. The computer has randomly determined that one of the [HE-4 answer minus 1] adults other than yourself should be selected for the rest of the interview. To help us select this person, do you know who has had the most recent birthday among these adults?

YES 1
 NO 2 (HE-8)

HE-7. Other than yourself then, which adult has had the most recent birthday?

[PROBE FOR GENDER (IF NOT OBVIOUS) AND AGE OF HH MEMBER SELECTED.]

NAME: _____

GENDER: MALE 1 AND AGE:
 FEMALE..... 2

GO TO HE-10.

HE-8. So that the computer can choose someone to interview, please tell me the first names and ages of the [FILL # FROM HE-4 MINUS 1] adults currently living in this household. Please do not include yourself. [IF NEEDED: "Include people who usually stay in this household, but are temporarily away on business, vacation, or in the hospital. Do not include persons who are away on full-time active military duty with the armed forces, students living away from home in their own apartment, or any other family member who may be in a nursing home or other institution."]

[IF NOT OBVIOUS, ASK: "Is {NAME} male or female?"]
 [IF R ANSWERS DK OR RF TO IDENTIFYING HH MEMBERS, EXIT INTERVIEW.]

<u>FIRST NAME</u>	<u>GENDER</u>	<u>AGE</u>
_____	MALE..... 1	
_____	FEMALE..... 2	_ _
_____	MALE..... 1	
_____	FEMALE..... 2	_ _
_____	MALE..... 1	
_____	FEMALE..... 2	_ _

BOX HE-2

RUN SELECTION ALGORITHM ON HH MEMBERS LISTED IN HE-8 TO SELECT EXTENDED RESPONDENT. THEN, GO TO HE-10.

HE-9. {What is your first name?/The other adult in the household has been selected to participate in the next part of the study. What is the other adult's name?}

[PROBE FOR GENDER (IF NOT OBVIOUS) AND AGE OF HH MEMBER SELECTED.]

NAME: _____

GENDER: MALE 1 AND AGE: |_|_|
 FEMALE..... 2

HE-10. Besides the number I called, do you have other telephone numbers in your household that are for regular telephone usage? Please exclude telephone numbers that are dedicated for business use, faxes, or modems and all cell phones.

YES 1
 NO 2

BOX HE-3

IF EXTENDED RESPONDENT = SCREENER RESPONDENT,
 GO TO XINTRO_1.
 OTHERWISE, CONTINUE.

HE-11. {(HH MEMBER) has been selected to participate in the next part of the study.} May I speak to (HH MEMBER)?

AVAILABLE 1 (XINTRO_1)
NOT AVAILABLE 2 (MAKE APPOINTMENT)

[XINTRO_1] {Hello, my name is [INTERVIEWER'S NAME] and I am calling for the National Cancer Institute. The main purpose of this study is to understand what people know about cancer and how they get their information about it. You may have received a letter from the National Cancer Institute introducing this study.} You have been selected to participate in this important research study. Your participation is voluntary, and you can refuse to answer any questions or withdraw from the study at any time. All information obtained will be kept confidential to the extent the law allows. The answers you give us will be used to improve the way we explain important issues about cancer to people like you. The interview will take about 20-25 minutes depending on your answers. {We know your time is important, so as a token of our appreciation, we will provide you with (\$10/\$20) once we complete the interview.}

HE-12. [AUTOFILL. ASK ONLY IF NECESSARY: First, what is your age?]

.....(HE-14)
AGE

DK.....999 (HE-13)
RF.....998 (HE-13)

HE-13. Are you...

less than 18 years old, 1 (END STATEMENT)
between 18 and 34, 2
35 to 39, 3
40 to 44, or 4
45 or older? 5

HE-14. [AUTOFILL. ASK ONLY IF NECESSARY: {Are you/Is NAME} male or female?]

MALE 1
FEMALE 2

GO TO NEXT SECTION.

END STATEMENT. Thank you for your time, those are all of the questions that I have for you today. If you have questions about cancer or just want some information about cancer, you can call 1-800-4-CANCER or go to the National Cancer Institute's web site at: www.cancer.gov

GROUP ASSIGNMENT (GA)

{We are interested in conducting this survey over the Internet in the future./We are giving some respondents the option to complete the questionnaire on the Internet.} So, I need to ask you a few questions about your access to the Internet.

[INTERNET REFERS TO ALL SERVICES OFFERED BY AN INTERNET SERVICE PROVIDER. IT INCLUDES THE USE OF E-MAIL, THE WORLD WIDE WEB, BULLETIN BOARDS, CHAT GROUPS, DISCUSSION GROUPS, NEWS GROUPS, ON-LINE ORDERING FACILITIES, FILE TRANSFER (FTP), WEB TV, REAL AUDIO, ETC.]

- GA-1. Do you ever go on-line to use the Internet or World Wide Web, or to send and receive e-mail?
YES 1
NO 2 (NEXT SECTION)

GA-2. Where do you go on-line from to use the Internet? Anywhere else?

[MARK ALL THAT APPLY.]

- HOME 11
WORK 12
SCHOOL 13
A PUBLIC LIBRARY 14
A COMMUNITY CENTER 15
SOMEONE ELSE'S HOUSE 16
SOME OTHER PLACE (SPECIFY) 91

BOX GA-1

IF GA-2 HAS ONLY 1 RESPONSE, GO TO BOX GA-2.
OTHERWISE, CONTINUE.

GA-3. Where do you use the Internet from most often?

- HOME 1
WORK 2
SCHOOL 3
A PUBLIC LIBRARY 4
A COMMUNITY CENTER 5
SOMEONE ELSE'S HOUSE 6
[PLACE SPECIFIED IN GA-2] 7

BOX GA-2

IF GA-2 = 11 (HOME), ASK GA-4A.
OTHERWISE, ASK GA-4B.

- GA-4A. When you use the Internet at home, do you mainly access it through . . .
- a telephone modem, 1
 - a cable or satellite modem, 2
 - a DSL modem, 3
 - a wireless device [PDA], or 4
 - some other way? (SPECIFY) _____ 91

GO TO BOX GA-3.

- GA-4B. When you use the Internet at [FILL GA-3], do you mainly access it through . . .
- a telephone modem or 1
 - some other way? (SPECIFY) _____ 91

BOX GA-3

IF RANDOMLY ASSIGNED TO CHOICE, GO TO GA-5
 IF RANDOMLY ASSIGNED TO INTERNET, GO TO GA-6
 OTHERWISE, GO TO NEXT SECTION.

- GA-5. To make participation in this study as convenient as possible for you, you have the choice of completing the rest of the questions over the telephone or on the Internet. Which would you prefer?

- TELEPHONE 1 (NEXT SECTION)
- INTERNET 2

- GA-6. {We would like to have you answer the rest of the questions on the Internet.} We would like to e-mail the information you need to access the questionnaire on the Internet. What is your e-mail address?

EMAIL: _____ (END 2)

- DOESN'T HAVE AN EMAIL ADDRESS (GA-7)
- DK (GA-7)
- RF (GA-7)

- GA-7. It is easier to give you the information for accessing the Internet questionnaire in writing, because you will need some detailed instructions. {What is your mailing address?/ I would like to confirm your address. I have recorded that it is [FILL WITH STREET ADDRESS.]}

[PROGRAMMER: FILL WITH AddressLine1]
 STREET ADDRESS1

- DK (END STATEMENT)
- RF (END STATEMENT)

[PROGRAMMER: FILL WITH AddressLine2]
STREET ADDRESS2

[PROGRAMMER: FILL WITH City]
CITY

|||
STATE

||| ||| ||| - ||| ||| |||
ZIP CODE

GO TO END2.

GA-8. Then, let me give you the information you need to access the web site over the phone. Do you have a pencil and paper? First, let me give you the web site address. It is [INSERT URL]. On the home page, you will be asked to log in with a unique name and password. Your login name is [FILL LOGIN] and your password is [FILL PASSWORD].

[END2] Thank you for your time today. Please call us at 1-800-###-#### if you have any questions about accessing the web site to complete the rest of the questions. If we haven't received your survey in 2 weeks, we will call you back to make sure you haven't had any problems getting onto the web site.

ATTACHMENT 2b

Extended Interview



HEALTH COMMUNICATION (HC)

MEDIA EXPOSURE

The next few questions are about various ways you might get information.

HC-01. On a typical weekday, about how many hours do you...

[IF LESS THAN ONE HOUR, ENTER 1.]

	<u>HOURS</u>
a. watch television?..... HC01aWatchTV	_ _
b. listen to the radio?..... HC01bListenRadio	_ _
c. use the Internet for personal reasons?..... HC01cUseInternet	_ _

HC-02. During a typical weekend, including both Saturday and Sunday, about how many hours do you....

[IF LESS THAN ONE HOUR, ENTER 1.]

	<u>HOURS</u>
a. watch television?..... HC02aWeekendWatchTV	_ _
b. listen to the radio?..... HC02bWeekendRadio	_ _
c. use the Internet for personal reasons?..... HC02cWeekendInternet	_ _

HC-03. In the past seven days, how many days did you...

	<u>DAYS</u>
a. read a newspaper?..... HC03aReadNewspaper	_
b. watch the national news on television?..... HC03bNationalNews	_
c. watch the local news on television?..... HC03cLocalNews	_

EXPOSURE TO HEALTH INFORMATION

Next, we want to know about various ways you might get health information.

HC-04. Some newspapers or general magazines publish a special section that focuses on health. In the past year, have you read health sections of the newspaper or of a general magazine?

HC04ReadHealthSection

YES.....	1
NO.....	2 (HC-06)

HC-05. About how often have you read such health sections in the past year? Would you say.....

HC05HowOftenHealthSection

once or more per week, or.....	1
less than once per week?.....	2

HC-06. In the past year, have you watched dramatic or comedy television programs which are mostly about doctors or hospitals?

HC06WatchHealthTV

- YES..... 1
- NO 2 (HC-08)

HC-07. How often have you watched such medical shows in the past year? Would you say....

HC07HowOftenHealthTV

- once or more per week, or 1
- less than once per week? 2

HC-08. Some local television news programs include special segments of their newscasts that focus on health issues. In the past year, have you watched health segments on the local news?

HC08HealthOnNews

- YES..... 1
- NO 2 (BOX HC-1)

HC-09. How often have you watched health segments on local news in the past year? Would you say....

HC09HowOftenHealthOnNews

- once or more per week, or 1
- less than once per week? 2

BOX HC-1

IF RESPONDENT DOES NOT USE THE
INTERNET, GO TO HC-12.
OTHERWISE, CONTINUE.

HC-10. Some people notice information about health on the Internet, even when they are not trying to find out about a health concern they have or someone in the family has. Have you read such health information on the Internet in the past year?

HC10NoticeInfo

- YES..... 1
- NO 2 (HC-12)

HC-11. About how often have you read this sort of information in the past year? Would you say....

HC11HowOftenNoticeInfo

- once or more per month, or..... 1
- less than once per month?..... 2

HC-12. How much attention do you pay to information about health or medical topics [FILL MEDIA SOURCE]? Would you say a lot, some, a little, or none? (How about [FILL MEDIA SOURCE]?)

[ASK IN RANDOM ORDER.]

	<u>A LOT</u>	<u>SOME</u>	<u>A LITTLE</u>	<u>NONE</u>
a. from a doctor or other health care professional	1	2	3	4
HC12aAttendDoctor				
b. from family or friends.....	1	2	3	4
HC12bAttendFamily				
c. in newspapers.....	1	2	3	4
HC12cAttendNewspaper				
d. in magazines.....	1	2	3	4
HC12dAttendMagazines				
e. on the radio.....	1	2	3	4
HC12eAttendRadio				
f. on the Internet.....	1	2	3	4
HC12fAttendInternet				
g. on television.....	1	2	3	4
HC12gAttendTV				

Now, I want to ask you how much you trust health information from these same sources.

HC-13. How much you would you trust information about health or medical topics [FILL SOURCE]? Would you say a lot, some, a little or not at all? (How about from [FILL SOURCE])?

[ASK IN SAME ORDER AS ASKED IN HC-12.]

	<u>A LOT</u>	<u>SOME</u>	<u>A LITTLE</u>	<u>NOT AT ALL</u>
a. from a doctor or other health care professional HC13aTrustDoctor	1	2	3	4
b. from family or friends..... HC13bTrustFamily	1	2	3	4
c. in newspapers..... HC13cTrustNewspaper	1	2	3	4
d. in magazines..... HC13dTrustMagazines	1	2	3	4
e. on the radio..... HC13eTrustRadio	1	2	3	4
f. on the Internet..... HC13fTrustInternet	1	2	3	4
g. on television..... HC13gTrustTV	1	2	3	4

INTERNET USAGE FOR HEALTH

BOX HC-2

IF DOES NOT USE INTERNET,
THEN GO TO INTRO TO HC-17.
OTHERWISE, CONTINUE.

HC-14. Here are some ways people use the Internet. Some people have done these things, but other people have not. In the past year, have you done the following things while using the Internet?

	<u>YES</u>	<u>NO</u>
a. Looked for health or medical information for yourself?	1	2
HC14aHealthInfoSelf		
b. Looked for health or medical information for someone else?	1	2
HC14bHealthInfoOther		
c. Bought medicine or vitamins on-line?	1	2
HC14cBuyMedicine		
d. Participated in an on-line support group for people with a similar health or medical issue?.....	1	2
HC14dSupportGroup		
e. Used e-mail or the Internet to communicate with a doctor or a doctor's office?.....	1	2
HC14eTalkDoctor		
f. Looked for information about physical activity or exercise?.....	1	2
HC14fExerciseInfo		
g. Looked for information about diet or nutrition?	1	2
HC14gDietInfo		
h. Looked for information about protecting yourself from the sun?.....	1	2
HC14hSunInfo		
i. Looked for information about quitting smoking?	1	2
HC14iSmokingInfo		
j. Bookmarked a health-related web site?	1	2
HC14jBookmarkedSite		
k. Done anything else health-related on the Internet? (SPECIFY) _____	1	2
HC14kAnythingElseOnline		

BOX HC-3

IF DID NOT LOOK FOR HEALTH INFO FOR SELF OR SOMEONE
ELSE ON INTERNET,
THEN GO TO INTRO TO HC-17.
OTHERWISE, CONTINUE.

HC-15. Have you ever talked to a doctor, nurse, or other health care provider about any kind of health information you have gotten from the Internet?

HC15TalkedDoctor

YES.....	1
NO	2 (INTRO TO HC-17)

HC-16. When you talked with a health care provider, how interested were they in hearing about the information you found on-line? Were they....

HC16DoctorInterested

very interested,	1
somewhat interested,.....	2
a little interested, or.....	3
not at all interested?.....	4

EXPOSURE TO SPECIFIC HEALTH ISSUES

The next questions are about some specific health issues. I'll ask you whether you've heard about them and where you heard about them.

HC-17. Within the past year, have you seen, heard, or read anything about preventing cancer?

HC17PreventCancer

YES..... 1
NO 2 (NEXT SECTION)

HC-18. You said you heard about preventing cancer. Can you recall one or two things that you have seen, heard or read in the past year about preventing cancer? (Anything else?)

a. FIRST RESPONSE: _____
HC18aFirstPreventCancer

b. SECOND RESPONSE: _____
HC18bSecondPreventCancer

HC-19. Now think about tests to detect colon cancer. Within the past year, have you seen, heard or read anything about tests to detect colon cancer?

HC19HeardOfTest

YES..... 1
NO 2 (BOX HC-4)

HC-20. You said you heard about tests to detect colon cancer. Can you recall one or two things that you have seen, heard or read in the past year about tests to detect colon cancer? Anything else?

a. FIRST RESPONSE: _____
HC20aFirstColonTest

b. SECOND RESPONSE: _____
HC20bSecondColonTest

BOX HC-4
RANDOMLY ASSIGN RESPONDENTS TO RECEIVE EITHER
NUTRITION OR EXERCISE SEQUENCE.

HC-21. Now think about {nutrition/exercise or physical activity} and cancer. Within the past year, have you seen, heard, or read anything about {nutrition/exercise or physical activity} and cancer?

HC21HeardDietExer

YES..... 1
NO 2 (NEXT SECTION)

HC-22. You said you heard about {nutrition/exercise or physical activity} and cancer. Can you recall one or two things that you have seen, heard or read in the past year about {nutrition/exercise or physical activity} and cancer? Anything else?

a. FIRST RESPONSE: _____
HC22aFirstDietExer

b. SECOND RESPONSE: _____
HC22bSecondDietExer

CANCER COMMUNICATION (CA)

TOUCHED BY CANCER

Now, I would like to ask you about your personal experience with cancer.

CA-01. Have you ever been told by a doctor that you had cancer?

CA01EverHadCancer

- YES..... 1
- NO 2 (CA-06)
- YES, BUT IT WAS A MIS-DIAGNOSIS 3 (CA-06)

CA-02. What type of cancer was it, or in what part of the body did the cancer start?

CA02TypeofSPsCancer

CA02TypeofSPsCancer_OS

[CODE ALL THAT APPLY.]

- BLADDER CANCER..... 10
- BREAST CANCER 11
- CERVICAL CANCER (CANCER OF THE CERVIX)..... 12
- COLON CANCER..... 13
- ENDOMETRIAL CANCER (CANCER OF THE UTERUS)..... 14
- HEAD AND NECK CANCER 15
- LEUKEMIA/BLOOD CANCER 16
- LUNG CANCER..... 17
- LYMPHOMA 18
- MELANOMA 19
- OTHER SKIN CANCER..... 20
- ORAL CANCER..... 21
- OVARIAN CANCER..... 22
- PANCREATIC CANCER..... 23
- PHARYNGEAL (THROAT) CANCER 24
- PROSTATE CANCER 25
- RECTAL CANCER..... 26
- RENAL (KIDNEY) CANCER 27
- OTHER (SPECIFY) _____ 91

CA-03. At what age or in what year were you first told that you had cancer?

CA03WhenDiagnosedCancer_Unit

CA03WhenDiagnosedCancer_Age

CA03WhenDiagnosedCancer_Year

[ENTER UNIT.]

UNIT

- AGE..... 1
- YEAR..... 2

[ENTER {AGE/YEAR}.]

AGE/YEAR

CA-04. Did you undergo treatment for your cancer?

CA04UndergoCancerTreatment

- YES..... 1
- NO 2 (CA-06)

CA-05. How long ago did you finish your treatment?

CA05HowLongFinishTreatment_Unit

CA05HowLongFinishTreatment

[ENTER UNIT.]

UNIT

- MONTHS 1
- YEARS..... 2
- STILL IN TREATMENT 3 (CA-06)

[ENTER NUMBER.]

NUMBER

CA-06. Have any of your brothers, sisters, parents, children, or other close family members ever had cancer?

CA06FamilyEverHadCancer

[IF INDICATE "DOESN'T HAVE FAMILY," CODE AS "NO FAMILY."]

- YES..... 1
- NO 2 (CA-08)
- NO FAMILY..... 3 (CA-08)

CA-07. What type of cancer was it?

CA07TypeFamilyCancer

[CODE ALL THAT APPLY.]

- BLADDER CANCER 10
- BREAST CANCER 11
- CERVICAL CANCER (CANCER OF THE CERVIX) 12
- COLON CANCER 13
- ENDOMETRIAL CANCER (CANCER OF THE UTERUS)..... 14
- HEAD AND NECK CANCER 15
- LEUKEMIA/BLOOD CANCER 16
- LUNG CANCER..... 17
- LYMPHOMA 18
- MELANOMA 19
- OTHER SKIN CANCER..... 20
- ORAL CANCER..... 21
- OVARIAN CANCER..... 22
- PANCREATIC CANCER..... 23
- PHARYNGEAL (THROAT) CANCER 24
- PROSTATE CANCER 25
- RECTAL CANCER..... 26
- RENAL (KIDNEY) CANCER 27
- OTHER (SPECIFY) 91

INFORMATION SEEKING ABOUT CANCER

Now, I want to ask you questions about looking for information on cancer. Please consider all sources of information such as the Internet, the library, friends, and health care professionals.

CA-08. Have you ever looked for information about cancer from any source?

CA08SeekCancerInfo

- YES..... 1
- NO 2

CA-09. Not including your doctor or other health care provider, has someone else ever looked for information about cancer for you?

CA09OtherSeekCancerInfo

- YES..... 1
- NO 2 (BOX CA-1)

CA-10. Who was that?

CA10WhoSeekCancerInfo

CA10WhoSeekCancerInfo_OS

[CODE ALL THAT APPLY.]

- SPOUSE..... 10
- OTHER FAMILY MEMBER..... 11
- FRIEND..... 12
- CO-WORKER..... 13
- INFORMATION SPECIALIST (E.G., LIBRARIAN)..... 14
- OTHER (SPECIFY) _____ 91

BOX CA-1

IF RESPONDENT HAS NOT LOOKED FOR INFORMATION FROM ANY SOURCE ON CANCER, NEITHER INDIVIDUALLY NOR THROUGH SOMEONE ELSE, THEN GO TO CA-17. OTHERWISE, CONTINUE.

Think about the most recent time you looked for cancer-related information from any source (either on your own or by someone else looking for you).

CA-11. About how long ago was that?

CA11LastLookCancerInfo_Unit

CA11LastLookCancerInfo

[ENTER UNIT.]

UNIT

- DAYS AGO..... 1
- WEEKS AGO..... 2
- MONTHS AGO..... 3
- YEARS AGO..... 4

[ENTER NUMBER.]

NUMBER

BOX CA-2
 IF SP HAS NOT LOOKED FOR INFORMATION ABOUT CANCER
 THEMSELF, GO TO CA-17.
 OTHERWISE, CONTINUE.

CA-12. The most recent time you wanted information on cancer, where did you go first?

CA12WhereLookCancerInfo

CA12WhereLookCancerInfo_OS

[IF SP HAS MADE MORE THAN ONE SEARCH, PROBE FOR THE MOST RECENT SEARCH.]

- BOOKS 1
- BROCHURES, PAMPHLETS, ETC. 2
- CANCER ORGANIZATION..... 3
- FAMILY 4
- FRIEND/CO-WORKER 5
- HEALTH CARE PROVIDER 6
- INTERNET 7
- LIBRARY..... 8
- MAGAZINES..... 9
- NEWSPAPERS..... 10
- RADIO 11
- TELEPHONE INFORMATION NUMBER (1-800 NUMBER)..... 12
- OTHER (SPECIFY) _____ 91

CA-13. What type of information were you looking for in your most recent search?

CA13WhatLookCancerInfo

BARRIERS TO CANCER INFORMATION SEEKING

CA-14. Based on the results of your most recent search for information on cancer, tell me how much you agree or disagree with the following statements.

[IF SP HAS MADE MORE THAN ONE SEARCH, PROBE FOR THE MOST RECENT SEARCH.]

	<u>STRONGLY AGREE</u>	<u>SOMEWHAT AGREE</u>	<u>SOMEWHAT DISAGREE</u>	<u>STRONGLY DISAGREE</u>
a. It took a lot of effort to get the information you needed. Would you say you.....	1	2	3	4
CA14aALotEffort				
b. You felt frustrated during your search for the information. (Would you say you...).....	1	2	3	4
CA14bFrustrated				
c. You were concerned about the quality of the information. (Would you say you...).....	1	2	3	4
CA14cConcernedQuality				
d. The information you found was too hard to understand. (Would you say you...).....	1	2	3	4
CA14cTooHardUnderstand				

BOX CA-3

IF RESPONDENT DOESN'T USE INTERNET,
GO TO CA-17.

IF RESPONDENT'S MOST RECENT SEARCH
WAS ON THE INTERNET, GO TO CA-16.
OTHERWISE, CONTINUE.

CANCER INFO ON THE INTERNET

CA-15. Have you ever visited an Internet web site to learn specifically about cancer?

CA15InternetForCancer

- YES..... 1
- NO 2 (CA-17)

CA-16. {Thinking about all the times you've looked for cancer information on the Internet}, How useful was the cancer-related information you got from the Internet? Would you say . . .

CA16UsefulInternetForCancer

- very useful,..... 1
- somewhat useful,..... 2
- a little useful, or..... 3
- not at all useful?..... 4

INFORMATION EFFICACY

CA-17. Overall, how confident are you that you could get advice or information about cancer if you needed it? Would you say...

CA17ConfidentGetCancerInfo

- completely confident, 1
- very confident,..... 2
- somewhat confident,..... 3
- a little confident, or..... 4
- not confident at all?..... 5

SOURCE PREFERENCES

[PROGRAMMER: IF RESPONDENT HAS NOT LOOKED FOR INFORMATION FROM ANY SOURCE EITHER INDIVIDUALLY OR THROUGH SOMEONE ELSE, THEN FILL CA-18 WITH "IMAGINE THAT YOU HAD" AND "WOULD." OTHERWISE, FILL WITH "THE NEXT TIME" AND "WILL."]

CA-18. {The next time you have/Imagine that you had} a strong need to get information about cancer. Where {will/would} you go first?

CA18WhereGoFirst

CA18WhereGoFirst_OS

- BOOKS 1
- BROCHURES, PAMPHLETS, ETC. 2
- CANCER ORGANIZATION..... 3
- FAMILY..... 4
- FRIEND/CO-WORKER..... 5
- HEALTH CARE PROVIDER 6
- INTERNET 7
- LIBRARY..... 8
- MAGAZINES..... 9
- NEWSPAPERS..... 10
- RADIO 11
- TELEPHONE INFORMATION NUMBER (1-800 NUMBER)..... 12
- OTHER (SPECIFY) 91

SOURCE RECOGNITION AND USE

CA-19. Before being contacted for this study, had you ever heard of...

	<u>YES</u>	<u>NO</u>	
a. the National Institutes of Health?	1	2	
CA19aNIH			
b. the American Cancer Society?.....	1	2	
CA19bACS			
c. the National Cancer Institute?	1	2	(CA-19e)
CA19cNCI			
d. the National Cancer Institute's Cancer Information Service?	1	2	
CA19dCIS			
e. the 1-800-4-Cancer information number?	1	2	
CA19eCancerHotline			
f. the National Smoking Quitline?.....	1	2	
CA19fSmokingQuitline			
g. the cancer.gov website?	1	2	
CA19gNCIWebsite			
h. the 1-800-ACS-2345 cancer information number?	1	2	
CA19hACS800Number			
i. Cancer Control of America?	1	2	
CA19iCancerControl			

BOX CA-4

IF CA-19d THROUGH CA-19h = NO,
THEN GO TO NEXT SECTION.

OTHERWISE, ASK CA-20 and CA-21 FOR EACH "YES"
ANSWER IN CA-19d THROUGH CA-19h.

CA-20. Did a health care provider refer you to it?

CA20ProviderReferredSource		
YES.....	1	
NO	2	

CA-21. Have you ever contacted it for information?

CA21ContactedSource		
YES.....	1	
NO	2	

BOX CA-5

IF RESPONDENT DID NOT CONTACT
ORGANIZATION EVEN THOUGH HEALTH CARE
PROVIDER RECOMMENDED IT
(CA-20=1 AND CA-21=2), CONTINUE.
OTHERWISE, GO TO NEXT SECTION.

CA-22. Why not?

CA22WhyNotContactSource

(NEXT SECTION)

CA-23. How useful was the information that was provided to you by {FILL}? Would you say.....

CA23UsefulInfoFromSource

- very useful..... 1
- somewhat useful..... 2
- a little useful, or..... 3
- not at all useful?..... 4

MENTAL MODEL OF CANCER (MM)

BOX MM-1

RANDOMLY ASSIGN RESPONDENT TO ONE OF THESE SPECIFIC CANCERS: LUNG, COLON, OR SKIN CANCER. FILL ALL QUESTIONS IN THIS SECTION WITH THE ASSIGNED CANCER.

PERSONAL RISK

MM-01. How likely do you think it is that you will develop {FILL} cancer in the future? Would you say your chance of getting {FILL} cancer is . . .

MM01ChanceGetCancer

- very low, 1
- somewhat low, 2
- moderate, 3
- somewhat high, or 4
- very high? 5

MM-02. Compared to the average person your age, would you say that you are . . .

MM02RelativeChanceCancer

- more likely to get {FILL} cancer, 1
- less likely, or 2
- about as likely? 3

MM-03. How often do you worry about getting {FILL} cancer? Would you say . . .

MM03FreqWorryCancer

- rarely or never, 1
- sometimes, 2
- often, or 3
- all the time? 4

PERCEPTIONS OF CAUSE/TIMELINE

MM-04. Please tell me how much you agree or disagree with the following statements.

	<u>STRONGLY AGREE</u>	<u>SOMEWHAT AGREE</u>	<u>SOMEWHAT DISAGREE</u>	<u>STRONGLY DISAGREE</u>
a. {FILL} cancer develops over a period of several years. Would you say you	1	2	3	4
MM04aCancerOveryears				
b. There are ways to slow down or disrupt the development of {FILL} cancer. (Would you say you....).....	1	2	3	4
MM04bSlowDownCancer				
c. {FILL} cancer is most often caused by a person's behavior or lifestyle. (Would you say you....)	1	2	3	4
MM04cBehaviorCauseCancer				
d. It seems like almost everything causes {FILL} cancer. Would you say you.	1	2	3	4
MM04dEverythingCausesCancer				

PREVENTION

MM-05.

	<u>STRONGLY AGREE</u>	<u>SOMEWHAT AGREE</u>	<u>SOMEWHAT DISAGREE</u>	<u>STRONGLY DISAGREE</u>
a. There's not much you can do to lower your chances of getting {FILL} cancer. Would you say you.....	1	2	3	4
MM05aCannotLowerChances				
b. There are so many different recommendations about preventing {FILL} cancer that it's hard to know which ones to follow. (Would you say you).....	1	2	3	4
MM05bTooManyRecommendations				

MM-06. Can you think of anything people can do to reduce their chances of getting {FILL} cancer?

MM06ReduceCancer
MM06ReduceCancer_OS

DETECTION

MM-07. Please tell me how much you agree or disagree with the following statement. People with {FILL} cancer would have pain or other symptoms prior to being diagnosed. Would you say you.....

strongly agree,	1
somewhat agree,	2
somewhat disagree, or.....	3
strongly disagree?.....	4

MM-08. What are the common symptoms of {FILL} cancer?

MM08SymptomsOfCancer

MM-09. Please tell me how much you agree or disagree with the following statements.

	<u>STRONGLY AGREE</u>	<u>SOMEWHAT AGREE</u>	<u>SOMEWHAT DISAGREE</u>	<u>STRONGLY DISAGREE</u>
a. Arranging to get checked for {FILL} cancer would be easy for you. Would you say you.....	1	2	3	4
MM09aCheckCancerEasy				
b. You are reluctant to get checked for {FILL} cancer because you fear you may have it. (Would you say you...).....	1	2	3	4
MM09bCheckCancerAfraid				
c. Getting checked regularly for {FILL} cancer increases the chances of finding cancer when it's easy to treat. (Would you say you...)	1	2	3	4
MM09cCheckEarlyDetect				

CONSEQUENCES

MM-10.

	<u>STRONGLY AGREE</u>	<u>SOMEWHAT AGREE</u>	<u>SOMEWHAT DISAGREE</u>	<u>STRONGLY DISAGREE</u>
a. {FILL} cancer is an illness that when detected early can typically be cured. (Would you say you...)	1	2	3	4
MM10aCancerCured				
b. {FILL} cancer is an illness that even if detected early will be fatal in a short period of time. (Would you say you...)	1	2	3	4
MM10bCancerFatal				

MM-11. Overall, how many people who develop {FILL} cancer do you think survive at least 5 years? Your best guess is fine. Would you say.....

MM11HowManySurvive

- less than a quarter, 1
- about a quarter, 2
- about half, 3
- about three quarters, or 4
- nearly all? 5

PROSTATE CANCER (PC)

BOX PC-1

IF RESPONDENT IS MALE, IS 45 OR OLDER, AND HAS
NOT HAD PROSTATE CANCER, CONTINUE.
OTHERWISE, GO TO NEXT SECTION

The next few questions are about getting tested for cancer. A Prostate-Specific Antigen test, also called a PSA test, is a blood test used to check men for prostate cancer.

PC-01. Have you ever heard of a PSA or prostate-specific antigen test?

PC01EverHeardPSATest

- YES..... 1
- NO 2 (NEXT SECTION)

PC-02. Have you ever had a PSA test?

PC02HadPSATest

- YES..... 1
- NO 2 (INTRO TO PC-04)
- HAD BLOOD TEST, BUT DK IF CHECKED PSA..... 3 (INTRO TO PC-04)

PC-03. When did you have your most recent PSA test?

PC03WhenPSATest

- A YEAR AGO OR LESS 1
- MORE THAN 1 BUT NOT MORE THAN 2 YEARS AGO 2
- MORE THAN 2 BUT NOT MORE THAN 5 YEARS AGO 3
- OVER 5 YEARS AGO 4

The next few questions are about discussions that health care providers might have had with you about the PSA test.

PC-04. Has a health care provider such as a doctor or nurse ever talked to you about a PSA test?

PC04ProviderTalkedPSA

- YES..... 1
- NO 2 (NEXT SECTION)

PC-05. Thinking about the last time a health care provider talked to you about a PSA test, which of the following statements best describes your health care provider's recommendation about PSA tests?

PC05ProviderRecommendPSA

- That you should have a PSA test..... 1
- That you should NOT have a PSA test..... 2
- Your health care provider did not make a recommendation about whether or not you should have a PSA test 3

PC-06. Thinking about the last time a health care provider talked to you about a PSA test, did your health care provider encourage you to ask questions or express any concerns you had about PSA testing? Would you say.....

PC06QuestionsAboutPSA

- yes, definitely, 1
- yes, somewhat, or..... 2
- no, not at all? 3
- DID NOT HAVE ANY QUESTION OR CONCERNS ABOUT PSA 4

PC-07. Thinking about the last time a health care provider talked to you about a PSA test, did this health care provider involve you as much as you wanted in deciding whether or not you should get a PSA test? Would you say.....

PC07InvolvePSA

- yes, definitely, 1
- yes, somewhat, or..... 2
- no, not at all? 3

CERVICAL CANCER (CV)

BOX CV-1
IF RESPONDENT IS FEMALE AND HAS NOT HAD
CERVICAL CANCER, CONTINUE. OTHERWISE, GO TO
NEXT SECTION

The next few questions are about getting tested for cancer. A Pap smear is a test for cancer of the cervix.

CV-01. Have you ever had a Pap smear?

- CV01HadPapSmear
- YES..... 1
 - NO..... 2 (CV-07)

CV-02. When did you have your most recent Pap smear?

- CV02WhenPapSmear
- A YEAR AGO OR LESS..... 1
 - MORE THAN 1 BUT NOT MORE THAN 3 YEARS AGO..... 2
 - MORE THAN 3 BUT NOT MORE THAN 5 YEARS AGO..... 3
 - OVER 5 YEARS AGO..... 4

CV-03. What was the main reason that you had this Pap smear?

- CV03WhyPapSmear
- ROUTINE ANNUAL PAP SMEAR OR PART OF
ROUTINE PHYSICAL EXAM..... 1
 - LAST PAP SMEAR WAS NOT NORMAL..... 2
 - A SPECIFIC PROBLEM..... 3
 - SOMETHING SHE HEARD / SAW / READ..... 4
 - SHE HAD NEVER HAD ONE AND THOUGHT SHE SHOULD..... 5
 - OTHER (SPECIFY)..... 91

CV-04. You said your most recent Pap smear was {INSERT TIME FRAME FROM CV-02}. How long before that Pap smear was the next most recent one?

- CV04PapSmearBeforeLast
- A YEAR AGO OR LESS..... 1
 - MORE THAN 1 BUT NOT MORE THAN 3 YEARS AGO..... 2
 - MORE THAN 3 BUT NOT MORE THAN 5 YEARS AGO..... 3
 - OVER 5 YEARS AGO..... 4

CV-05. Have you had a hysterectomy?

- CV05Hysterectomy
- [IF NEEDED: A hysterectomy is an operation to remove the uterus (womb).]
- YES..... 1 (CV-07)
 - NO..... 2

CV-06. When do you expect to have your next Pap smear?

CV06WhenNextPapSmear

- A YEAR OR LESS FROM NOW..... 1
- MORE THAN 1 BUT NOT MORE THAN 3 YEARS FROM NOW..... 2
- MORE THAN 3 BUT NOT MORE THAN 5 YEARS FROM NOW..... 3
- OVER 5 YEARS FROM NOW..... 4
- AM NOT PLANNING TO HAVE ANOTHER..... 5
- IF I HAVE SYMPTOMS..... 6
- WHEN DOCTOR / HEALTH PROVIDER RECOMMENDS..... 7

CV-07. How often do you think a woman your age should have a Pap smear?

CV07HowOftenPapSmear

- MORE THAN TWICE A YEAR..... 1
- TWICE A YEAR / EVERY SIX MONTHS..... 2
- ONCE A YEAR..... 3
- EVERY TWO YEARS..... 4
- EVERY THREE YEARS..... 5
- MORE THAN EVERY THREE YEARS..... 6
- NEVER..... 7

CV-08. Most medical organizations now recommend a Pap smear every three years for healthy adult women. Have you heard about this change in guidelines?

CV08GuidelinesChange

- YES..... 1
- NO..... 2

BOX CV-2

IF RESPONDENT SAID SHE DOES NOT PLAN TO
HAVE ANOTHER PAP SMEAR, GO TO CV-10.
OTHERWISE, CONTINUE.

CV-09. Would you agree to have Pap smears less frequently than you currently do if your health care provider recommended it?

CV09LessFrequentPapSmear

- YES..... 1
- NO..... 2

CV-10. Have you ever been treated for venereal warts or condyloma?

CV10TreatedWarts

- YES..... 1
- NO..... 2

CV-11. Have you ever heard of HPV? HPV stands for Human Papillomavirus.

CV11HeardHPV

- YES..... 1
- NO..... 2 (NEXT SECTION)

CV-12. Have you ever been told by a health care provider that you had HPV infection?

CV12EverHadHPV

- YES..... 1
- NO..... 2

CV-13. Next, I'm going to ask your opinion about HPV.

	<u>YES</u>	<u>NO</u>
a. Do you think that HPV causes cervical cancer?	1	2
CV13aHPVCauseCancer		
b. Do you think that HPV is a sexually transmitted disease?	1	2
CV13bHPVSTD		
c. Do you think that HPV infection is rare?	1	2
CV13cHPVRare		
d. Do you think that HPV will often go away on its own without treatment?.....	1	2
CV13dHPVGoAway		
e. Do you think HPV can cause abnormal Pap smears?.....	1	2
CV13eHPVCauseAbnormalPap		
f. Do you think that HPV can affect a woman's ability to get pregnant?	1	2
CV13fHPVAffectPregnancy		

BREAST CANCER (BC)

BOX BC-1

IF RESPONDENT IS MALE, IS UNDER 35 YEARS OLD, OR HAS
HAD BREAST CANCER, GO TO NEXT SECTION.
OTHERWISE, CONTINUE.

The next few questions are about breast cancer.

BC-01. A mammogram is an x-ray of each breast to look for breast cancer. Have you ever had a mammogram?

- BC01HadMammogram
- YES..... 1
 - NO..... 2 (BC-03)

BC-02. When did you have your most recent mammogram to check for breast cancer?

- BC02WhenMammogram
- A YEAR AGO OR LESS..... 1
 - MORE THAN 1 BUT NOT MORE THAN 2 YEARS AGO..... 2
 - MORE THAN 2 BUT NOT MORE THAN 5 YEARS AGO..... 3
 - OVER 5 YEARS AGO..... 4

BC-03. About how often do you examine your breasts for lumps?

BC03ExamineBreasts

[ENTER NUMBER. IF NEVER, ENTER 95.]

TIMES

UNIT

[ENTER UNIT.]

- PER DAY..... 1
- PER WEEK..... 2
- PER MONTH..... 3
- NEVER..... 4

COLON CANCER (CC)

BOX CC-1
IF RESPONDENT HAS HAD COLON CANCER,
GO TO THE NEXT SECTION.
OTHERWISE, CONTINUE.

The next questions are about colon cancer.

CC-01. Can you think of any tests that detect colon cancer? Anything else?

CC01TestsForColonCancer

CC01TestsForColonCancer_OS

[CODE ALL THAT APPLY. IF R DOES NOT KNOW NAME OF TEST, ENTER DESCRIPTION OF TEST IN OTHER, SPECIFY.]

BARIUM ENEMA	10
BIOPSY.....	11
STOOL BLOOD TEST/FECAL OCCULT BLOOD TEST	12
COLONOSCOPY.....	13
DIGITAL RECTAL EXAM.....	14
PROCTOSCOPY.....	15
SIGMOIDOSCOPY	16
OTHER (SPECIFY) _____	91
NO/NOTHING	95

BOX CC-2
IF RESPONDENT IS LESS THAN 45 YEARS OLD,
GO TO NEXT SECTION.
OTHERWISE, CONTINUE.

CC-02. Has a doctor, nurse or other health professional ever advised you to get a test to check for colon cancer?

CC02AdviseCheckColonCancer

YES.....	1
NO	2

CC-03. A stool blood test, also known as a Fecal Occult Blood Test, is a test done to check for colon cancer. It is done at home using a set of 3 cards to determine whether the stool contains blood. Have you ever done this test using a home kit?

CC03HadStoolBlood

YES.....	1
NO	2 (CC-05)

CC-04. When did you do your most recent stool blood test using a home kit to check for colon cancer?

CC04WhenStoolBlood

A YEAR AGO OR LESS	1
MORE THAN 1 BUT NOT MORE THAN 2 YEARS AGO	2
MORE THAN 2 BUT NOT MORE THAN 5 YEARS AGO	3
OVER 5 YEARS AGO.....	4

CC-05. A sigmoidoscopy and a colonoscopy are both tests that examine the bowel by inserting a tube in the rectum. Have you ever had either a colonoscopy or a sigmoidoscopy?

CC05HadSigCol

- YES 1
- NO 2 (NEXT SECTION)

CC-06. When did you have your most recent sigmoidoscopy or colonoscopy to check for colon cancer?

CC06WhenSigCol

- A YEAR AGO OR LESS 1
- MORE THAN 1 BUT NOT MORE THAN 5 YEARS AGO 2
- MORE THAN 5 BUT NOT MORE THAN 10 YEARS AGO 3
- OVER 10 YEARS AGO 4

SKIN CANCER (SC)

BOX SC-1
 IF RESPONDENT HAS HAD MELANOMA OR SKIN CANCER,
 GO TO NEXT SECTION.
 OTHERWISE, CONTINUE.

The next few questions are about things people might do to protect themselves from the sun.

SC-01. When you go outside for more than 1 hour on a warm, sunny day, how often do you...

[IF R DOES NOT GO OUTSIDE ON A SUNNY DAY FOR MORE THAN ONE HOUR, CODE 95.]

	<u>ALWAYS</u>	<u>OFTEN</u>	<u>SOMETIMES</u>	<u>RARELY</u>	<u>NEVER</u>	
a. wear sunscreen? Would you say	1	2	3	4	5	95 (SC-02)
SC01aSunscreen						
b. stay in the shade? (Would you say...).....	1	2	3	4	5	
SC01bShade						
c. wear a hat that shades your face, ears and neck? (Would you say...)	1	2	3	4	5	
SC01cHat						
d. wear a long-sleeve shirt? (Would you say...).....	1	2	3	4	5	
SC01dLongSleeveShirt						
e. wear long pants? (Would you say...).....	1	2	3	4	5	
SC01eLongPants						

SC-02. How many times in the past year have you used indoor tanning devices such as a sun lamp, a sun bed or a tanning booth?

SC02TanningDevices

0 TIMES	1
1-2 TIMES	2
3-10 TIMES	3
11-24 TIMES	4
25 TIMES OR MORE	5

SC-03. How many times in the past year have you used sunless tanning products? These are products that you either have sprayed on or which you apply to darken the color of your skin.

SC03TanningProducts

0 TIMES	1
1-2 TIMES	2
3-10 TIMES	3
11-24 TIMES	4
25 TIMES OR MORE	5

SC-04. What is the recommended minimum Sun Protection Factor, or SPF, that should be used in a sunscreen to protect your skin?

SC04RecommendedSPF

|_|_|
 NUMBER

TOBACCO USE (TU)

TOBACCO SCREENER

ALL RESPONDENTS

Now, I'd like to ask you about your use of tobacco.

TU-01. Have you smoked at least 100 cigarettes in your entire life?

[IF NEEDED: 5 Packs = 100 Cigarettes.]

TU01Smoke100

- YES 1
- NO 2 (TU-16)

EVER SMOKERS

TU-02. Do you now smoke cigarettes . . .

TU02SmokeNow

- every day, 1
- some days, or 2 (TU-4)
- not at all? 3 (TU-11)
- DK 9 (TU-16)
- RF 8 (TU-16)

CURRENT EVERY DAY SMOKERS

TU-03. On the average, how many cigarettes do you now smoke a day?

TU03SmokeDayAlways

[IF NEEDED: 1 Pack = 20 Cigarettes.]

[IF LESS THAN ONE A DAY, ENTER 0. IF 76 OR MORE, ENTER 76.]

NUMBER OF CIGARETTES

GO TO TU-7.

CURRENT SOME DAY SMOKERS

TU-04. On how many of the past 30 days did you smoke cigarettes?

TU04SmokePast30Days

DAYS

TU-05. On the average, on those {FILL WITH TIME PERIOD FROM TU-04} days, how many cigarettes did you usually smoke each day?

TU05SmokeDaySometimes

[IF NEEDED: 1 Pack = 20 Cigarettes.]

[IF LESS THAN ONE A DAY, ENTER 0. IF 76 OR MORE, ENTER 76.]

NUMBER OF CIGARETTES

QUIT ATTEMPTS

BOX TU-1
IF SMOKED 12 OR MORE OF THE PAST 30 DAYS (TU-04=>12), GO TO TU-07. OTHERWISE, CONTINUE.

TU-06. During the past 12 months, have you tried to quit smoking completely?

TU06TriedQuit

YES..... 1
NO 2

GO TO TU-09.

ALL CURRENT SMOKERS

TU-07. Have you ever stopped smoking for one day or longer because you were trying to quit smoking?

TU07StoppedSmokeTryQuit

YES..... 1
NO 2 (TU-09)

TU-08. How many times during the past 12 months have you stopped smoking for one day or longer because you were trying to quit smoking?

TU08TimesStoppedSmoke

TIMES

TU-09. During the past 12 months, did any doctor, dentist, nurse or other health care professional advise you to quit smoking?

TU09AdviseQuitSmoke

YES..... 1
NO 2
DID NOT SEE HEALTH CARE PROVIDER IN LAST 12 MONTHS 95

TU-10. Are you seriously considering quitting smoking within the next 6 months?

TU10ConsiderQuit

YES..... 1
NO 2

BOX TU-2
IF SMOKE EVERY DAY OR SOME DAYS, GO TO TU-16. OTHERWISE, CONTINUE.

FORMER SMOKERS

TU-11. About how long has it been since you completely quit smoking cigarettes?

TU11WhenQuitSmoke

TIME

UNIT

[ENTER UNIT.]

- DAYS 1
- WEEKS 2
- MONTHS 3
- YEARS 4

TU-12. Have you ever smoked cigarettes every day for at least 6 months?

TU12SmokeEveryDay6Months

- YES 1
- NO 2

TU-13. On average on the days you last smoked, how many cigarettes did you usually smoke each day?

TU13SmokeDayFormer

[IF NEEDED: 1 Pack = 20 Cigarettes.]

[IF LESS THAN ONE A DAY, ENTER 0. IF 76 OR MORE, ENTER 76.]

NUMBER OF CIGARETTES

BOX TU-3

IF QUIT SMOKING OVER 1 YEAR AGO, GO TO TU-16.
 IF QUIT SMOKING 1 YEAR AGO OR LESS,
 CONTINUE.

TU-14. Around this time 12 months ago, were you smoking cigarettes.....

TU14HowOftenFormerSmoke

- every day, 1
- some days, or 2
- not at all? 3

TU-15. During the past 12 months, did any doctor, dentist, nurse or other health care professional advise you to quit smoking?

TU15FormerSmokeAdviseQuit

- YES 1
- NO 2
- DID NOT SEE HEALTH CARE PROFESSIONAL 95

ALL RESPONDENTS

TU-16. I am going to read you some statements people might make about smoking. For each, tell me how much you agree or disagree, or if you have no opinion.

	<u>STRONG LY AGREE</u>	<u>SOMEWH AT AGREE</u>	<u>SOMEWH AT DISAGRE E</u>	<u>STRONGL Y DISAGRE E</u>	<u>NO OPINI ON</u>
a. Exercise can undo most of the effects of smoking. Would you say you					
TU16aExercise	1	2	3	4	5
b. Vitamins can undo most of the effects of smoking. (Would you say you...)	1	2	3	4	5
TU16bVitamins					
c. There's no risk of getting cancer if someone only smokes a few years. (Would you say you...).....	1	2	3	4	5
TU16cFewYears					
d. Whether a person gets lung cancer depends more on genes than anything else. (Would you say you...).....	1	2	3	4	5
TU16dGenes					

BOX TU-4

IF NEVER SMOKED (TU-01=2)
OR IF TU-02=DK OR RF, GO TO NEXT SECTION.
OTHERWISE, CONTINUE.

EVER SMOKERS

TU-17. If a new cigarette were advertised as less harmful than current cigarettes, how interested would you be in trying it?
Would you say . . .

TU17WouldTryLessHarmfulCig	
very interested,	1
somewhat interested, or.....	2
not interested?	3

TU-18. Now, I'm going to ask about new tobacco products that have been recently introduced. Have you ever heard of a tobacco product called....(How about...)

	<u>YES</u>	<u>NO</u>
a. Eclipse?	1	2
TU18aHeardEclipse		
b. Accord?.....	1	2
TU18bHeardAccord		
c. Arriva?	1	2
TU18cHeardArriva		
d. Exalt?.....	1	2
TU18dHeardExalt		
e. Revel?.....	1	2
TU18eHeardRevel		
f. Omni?	1	2
TU18fHeardOmni		
g. Advance?.....	1	2
TU18gHeardAdvance		
h. Stonewall?	1	2
TU18hHeardStonewall		
i. Scor?	1	2
TU18iHeardScor		

BOX TU-5

FOR EACH "YES" RESPONSE IN TU-18, ASK TU-19 BEFORE MOVING ON TO NEXT ITEM IN TU-18.

IF TU-18a THROUGH TU-18i = NO, THEN GO TO NEXT SECTION.

TU-19. How did you hear about {FILL TU-18}?

TU19HowHeardNewProduct
[CODE ALL THAT APPLY.]

FROM A DOCTOR OR HEALTH CARE PROVIDER	10
FROM FAMILY OR FRIENDS	11
IN A NEWSPAPER	12
IN A MAGAZINE	13
ON THE RADIO	14
ON THE INTERNET	15
ON TELEVISION	16
OTHER (SPECIFY) _____	91

TU-20. Have you ever tried {this product/any of these products}?

TU20TriedNewProduct

YES.....	1
NO	2 (TU-24)

TU-21. Do you now use {this product/any of these products}.....

TU21NowUseNewProduct

every day	1
some days, or	2
not at all?	3

BOX TU-6

IF NOT A CURRENT SMOKER AND NEVER USED NEW PRODUCTS, GO TO TU-24.

IF FORMER USER OF NEW PRODUCT (TU-21=3), THEN USE PAST TENSE IN TU-22 AND TU-23.

IF CURRENT USER OF NEW PRODUCT (TU-21=1 OR 2), THEN USE PRESENT TENSE IN TU-22 AND TU-23.

TU-22. {Now that you are using/When you tried or used} {this product/these products} {did/do} you smoke.....

TU22HowOftenNewProduct

- less of your regular brand of cigarettes,..... 1
- about the same number of your regular brand of cigarettes, or 2
- more of your regular brand of cigarettes? 3

TU-23. What is the main reason you {use/tried or used} {this product/these products}?

TU23WhyUseNewProduct

- INSTEAD OF QUITTING, AS A WAY TO REDUCE HEALTH RISKS 1
- AS A WAY OF CUTTING DOWN THE NUMBER OF REGULAR CIGARETTES SMOKED..... 2
- TO HELP YOU QUIT SMOKING 3
- BECAUSE OF THE TASTE 4
- BECAUSE LOWER COSTS/CHEAPER THAN REGULAR CIGARETTES 5
- OUT OF CURIOSITY..... 6
- BECAUSE NOT AS STRONG/LESS NICOTINE/LIGHTER/LESS TAR THAN REGULAR CIGARETTES 7
- BECAUSE LESS HARMFUL TO USE AROUND FAMILY/FRIENDS/CHILDREN THAN REGULAR CIGARETTES 8
- BECAUSE CAN USE IN PLACES WEHRE CAN'T SMOKE REGULAR CIGARETTES 9
- OTHER (SPECIFY) 91

TU-24. As far as you know, {is this product/are these products}.....

TU24HowHarmfulNewProduct

- less harmful than regular cigarettes, 1
- equally harmful, or 2
- more harmful than regular cigarettes? 3

ENERGY BALANCE (EB)

NUTRITION

These next few questions are about how often you ate or drank different kinds of foods during the past month, for example, twice a week, three times a month, and so forth. Include all foods you ate or drank, both at home and away from home.

EB-01. During the past month, how often did you drink 100% fruit juice such as orange, apple, and grape juices? Do not include fruit drinks like Kool-Aid or Hi-C.

EB01FruitJuice

EB01FruitJuice_Unit

[ENTER NUMBER. IF NEVER, ENTER 95.]

TIMES

UNIT

[ENTER UNIT.]

- PER DAY 1
- PER WEEK 2
- PER MONTH 3
- NEVER 95

EB-02. During the past month, how often did you eat fruit? Include fresh, canned, or frozen fruit.

EB02Fruits

EB02Fruits_Unit

[ENTER NUMBER. IF NEVER, ENTER 95.]

TIMES

UNIT

[ENTER UNIT.]

- PER DAY 1
- PER WEEK 2
- PER MONTH 3
- NEVER 95

EB-03. During the past month, how often did you eat potatoes? Do not include things like fried potatoes, french fries, or rice.

EB03Potatoes

EB03Potatoes_Unit

[ENTER NUMBER. IF NEVER, ENTER 95.]

TIMES

UNIT

[ENTER UNIT.]

- PER DAY 1
- PER WEEK 2
- PER MONTH 3
- NEVER 95

EB-04. During the past month, how often did you eat vegetables other than potatoes? Include things like salad, cooked dried beans, corn, and broccoli.

EB04Vegetables

EB04Vegetables_Unit

[ENTER NUMBER. IF NEVER, ENTER 95.]

TIMES

UNIT

[ENTER UNIT.]

- PER DAY 1
- PER WEEK 2
- PER MONTH 3
- NEVER 4

EB-05. How many servings of fruits and vegetables do you think a person should eat each day for good health?

EB05NumberServings

[IF R GIVES RANGE, PROBE FOR AN EXACT NUMBER. IF DON'T KNOW, DO NOT PROBE.]

SERVINGS

EXERCISE

The next few questions are about your exercise, recreation, and physical activity patterns.

EB-06. In a typical week, how many days do you do any moderate-intensity physical activity or exercise comparable to walking as if you were in a hurry?

EB06TimesModerateExercise

DAYS

NONE 95 (EB-08)

EB-07. On the days that you do any moderate physical activity or exercise, how long are you typically doing these activities?

EB07HowLongModerateExercise

EB07HowLongModerateExercise_Unit

NUMBER

UNIT

[ENTER UNIT.]

- MINUTES 1
- HOURS 2

EB-08. How many days a week of physical activity or exercise are recommended for the average adult to stay healthy?

EB08RecommendDaysExercise

DAYS

NONE 95 (EB-10)

EB-09. On those days, how long should the average adult be physically active to stay healthy?

EB09RecommendTimeExercise

EB09RecommendTimeExercise_Unit

NUMBER

UNIT

[ENTER UNIT.]

MINUTES..... 1
HOURS..... 2

EB-10. As far as you know, does physical activity or exercise increase or decrease the chances of getting some types of cancer, or does it not make much difference?

EB10ExerciseLowerRiskCancer

INCREASES CHANCES OF CANCER..... 1
DECREASES CHANCES OF CANCER..... 2
MAKES NO DIFFERENCE..... 3

WEIGHT LOSS

EB-11. Have you tried to lose any weight in the past year?

EB11LostWeight

YES..... 1
NO..... 2

EB-12. Are you aware of low carbohydrate, high protein diets such as the Atkins Diet, the Zone, Sugar Busters, or the South Beach Diet?

EB12AwareLowCarb

YES..... 1
NO..... 2 (BOX EB-1)

EB-13. Have you tried a low carbohydrate, high protein diet in the past year?

EB13TriedCarbDiet

YES..... 1
NO..... 2 (EB-15)

EB-14. What types of low carbohydrate, high protein diets did you try?

EB14WhichLowCarbTried

[CODE ALL THAT APPLY.]

ATKINS DIET..... 10
THE ZONE..... 11
SUGAR BUSTERS..... 12
THE SOUTH BEACH DIET..... 13
OTHER (SPECIFY):..... 91

EB-15. Do you think that a low carbohydrate, high protein diet is a healthy way to lose weight?

EB15LowCarbDietHealthy

YES..... 1
NO..... 2

BOX EB-1

RANDOMIZE RESPONDENTS TO RECEIVE
EITHER NUTRITION OR EXERCISE SERIES IN
EB-16 THROUGH EB-18.

DIET AND EXERCISE INFORMATION

EB-16. When you hear or read a new recommendation about {nutrition/physical activity or exercise}, are you more likely to pay attention to it or to ignore it?

- EB16PayAttention
- PAY ATTENTION TO IT 1
 - IGNORE IT..... 2 (EB-18)

EB-17. Think about the last time you heard a new recommendation about {nutrition/physical activity or exercise}. Which of the following things did you do in response to the new recommendation?

- EB17ChangeBehavior
- I changed what I do,..... 1
 - I did not change what I do, or..... 2
 - I waited to get more information..... 3

EB-18. Please tell me whether you agree or disagree with the following statement. There are so many different recommendations about {nutrition/physical activity or exercise} that it's hard to know which ones to follow. Would you say you

- EB18TooManyRecommend
- strongly agree, 1
 - somewhat agree, 2
 - somewhat disagree, 3
 - strongly disagree, or 4
 - do you have no opinion? 5

BOX EB-2

IF RESPONDENTS WAS RANDOMIZED TO
RECEIVE NUTRITION SERIES, GO TO EB-20.
OTHERWISE, CONTINUE.

EB-19. Please tell me whether you agree or disagree or whether you have no opinion about the following statement. People who are overweight can lose a significant amount of weight by doing 30 minutes of moderate activities such as brisk walking on most .days of the week. Would you say you . . .

- EB19Lose30Minutes
- strongly agree, 1
 - somewhat agree, 2
 - somewhat disagree, 3
 - strongly disagree, or 4
 - do you have no opinion? 5

HEIGHT AND WEIGHT

EB-20. About how tall are you without shoes?

EB20Height_Feet

EB20Height_Inches

[ENTER FEET.]

--	--	--

FEET

[ENTER INCHES. ROUND FRACTIONS OF INCHES DOWN TO WHOLE INCH.]

--	--	--

INCHES

EB-21. About how much do you weigh without shoes?

EB21Weight

EB21Weight_Unit

[ROUND FRACTIONS UP TO WHOLE NUMBER.]

--	--	--	--

NUMBER

--

UNIT

[ENTER UNIT.]

- POUNDS..... 1
- KILOGRAMS..... 2

HEALTH STATUS (HS)

HS-01. In general, would you say your health is...

HS01GeneralHealth

- excellent, 1
- very good, 2
- good, 3
- fair, or 4
- poor? 5

DEPRESSION

Now, I am going to ask you some questions about feelings you may have experienced over the past 30 days.

HS-02. During the past 30 days, how often did you feel [FEELING]? Would you say all of the time, most of the time, some of the time, a little of the time, or none of the time?

	<u>ALL OF THE TIME</u>	<u>MOST OF THE TIME</u>	<u>SOME OF THE TIME</u>	<u>A LITTLE OF THE TIME</u>	<u>NONE OF THE TIME</u>
a. so sad that nothing could cheer you up.....	1	2	3	4	5
HS02aSad					
b. nervous.....	1	2	3	4	5
HS02bNervous					
c. restless or fidgety.....	1	2	3	4	5
HS02cRestless					
d. hopeless.....	1	2	3	4	5
HS02dHopeless					
e. that everything was an effort.....	1	2	3	4	5
HS02eEffort					
f. worthless.....	1	2	3	4	5
HS02fWorthless					

BOX HS-1

IF RESPONDENT HAD ANY OF THE FEELINGS IN HS-02
ALL, MOST, OR SOME OF THE TIME, CONTINUE.
OTHERWISE, GO TO HS-04.

HS-03. We just talked about a number of feelings you had during the past 30 days. Altogether, how much did these feelings interfere with your life or activities? Would you say . . .

HS03DepressionInterfere

- a lot, 1
- some, 2
- a little, or 3
- not at all? 4

HEALTH COVERAGE

HS-04. Do you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?

HS04HealthInsurance

- YES 1
- NO 2

HS-05. During the past 12 months, not counting times you went to an emergency room, how many times did you go to a doctor, nurse or other health care provider to get care for yourself?

HS05FreqGoProvider

- 1 TIME 1
- 2 TIMES 2
- 3 TIMES 3
- 4 TIMES 4
- 5-9 TIMES 5
- 10 OR MORE TIMES 6
- NONE 95

SOCIAL NETWORKS (SN)

Next, I want to ask you about your participation in community organizations. By community organization we mean any group that you might participate in such as church, sports leagues, self-help groups, service clubs, or professional organizations.

SN-01. How many community organizations are you currently a member of?

SN01CommunityOrgs

|||

NUMBER

NONE 95 (SN-03)

SN-02. {Does this/Do any of these} community organization{s} provide you with information on health?

SN02CommOrgsHealthInfo

YES..... 1

NO 2

SN-03. Do you have friends or family members that you talk to about your health?

SN03TalkHealthFriends

YES..... 1

NO 2 (SN-05)

SN-04. How frequently do you talk to these friends or family members about health? Would you say....

SN04FrequencyTalkHealthFriends

very frequently, 1

somewhat frequently, or 2

not very frequently? 3

SN-05. How many people live near you who you can rely on in case you need a ride to visit your health care provider?

SN05RideToProvider

[ENTER NUMBER. IF NONE, ENTER 95.]

|||

NUMBER

SN-06. Not including funerals and weddings, how often do you attend religious services? Would you say....

SN06ReligiousServices

every week, 1

once or twice a month, 2

a few times a year, or 3

never? 4

DEMOGRAPHICS (DM)

I have a few final questions about you and your household.

DM-01. Are you currently . . .

DM01MainActivity

- employed for wages,..... 1
- self-employed,..... 2
- out of work for more than one year, 3
- out of work for less than one year, 4
- a homemaker, 5
- a student, 6
- retired, or..... 7
- unable to work?..... 8

DM-02. Are you . . .

DM02MaritalStatus

- married,..... 1
- divorced, 2
- widowed, 3
- separated, 4
- never been married, or..... 5
- a member of an unmarried couple? 6

DM-03. What is the highest level of school you completed?

DM03Education

- NEVER ATTENDED SCHOOL OR ONLY ATTENDED
NUSERY SCHOOL/KINDERGARTEN..... 1
- GRADES 1 THROUGH 5 (ELEMENTARY) 2
- GRADES 6 THROUGH 8 (MIDDLE)..... 3
- GRADES 9 THROUGH 12 (SOME HIGH SCHOOL BUT NO DIPLOMA) 4
- HIGH SCHOOL GRADUATE (HIGH SCHOOL DIPLOMA OR
EQUIVALENT, E.G., GED, FOREIGN EQUIVALENT) 5
- VOCATIONAL OR TRADE SCHOOL GRADUATE 6
- SOME COLLEGE, BUT NO DEGREE 7
- ASSOCIATE DEGREE IN COLLEGE 8
- BACHELOR'S DEGREE 9
- MASTER'S DEGREE 10
- PROFESSIONAL SCHOOL OR DOCTORATE DEGREE (MD, DDS,
JD, DVM, Ph.D., EdD, etc)..... 11

DM-04. Are you Hispanic or Latino?

DM04Hispanic

- YES..... 1
- NO 2

DM-05. Which one or more of the following would you say is your race? Are you . . .

DM05Race

[CODE ALL THAT APPLY. IF R SAYS "HISPANIC," PROBE FOR ONE OF THE LISTED RACE CATEGORIES.]

- American Indian or Alaska Native, 10
- Asian, 11
- Black or African American, 12
- Native Hawaiian or other Pacific Islander, or 13
- White? 14

DM-06. Where you born in the United States?

DM06BornInUSA

- YES 1 (BOX DM-1)
- NO 2

DM-07. In what year did you come to the United States?

DM07YearCameToUSA

YEAR

BOX DM-1

IF RESPONDENT IS NOT HISPANIC,
GO TO DM-09
OTHERWISE, CONTINUE.

DM-08. How comfortable do you feel speaking English? Would you say....

DM08ComfortWithEnglish

- completely comfortable, 1
- very comfortable, 2
- somewhat comfortable, 3
- a little comfortable, or 4
- not at all comfortable? 5
- DOES NOT SPEAK ENGLISH 95

DM-09. Do you currently rent or own your home?

DM09RentOrOwn

- OWN 1
- RENT 2 (INTRO TO DM-11)
- OCCUPIED WIHTOUT PAYING MONETARY RENT 3 (INTRO TO DM-11)

DM-10. Is the mortgage fully paid?

DM10MortgagePaid

- YES 1
- NO 2

Next, I want to ask you some questions about your family. By family we mean people who are living in your household who are related to you by blood, marriage, or adoption.

DM-11. Including yourself, how many people live in your household?

DM11NumberInHH

(IF "1", GO TO DM-14)
 NUMBER

DM-12. How many people in your household are related to you by blood, marriage, or adoption?

DM12NumberInHHRRelated
 | | |
 NUMBER

DM-13. How many of these family members are under the age of 18?

DM13NumberUnder18
 | | |
 NUMBER

DM-14. {Thinking about members of your family living in this household, what/What} is your {combined} annual income, meaning the total pre-tax income from all sources earned in the past year?

DM14Income
 \$ | | | | | | | | | |

IF DK OR RF, ASK: Is your annual household income from all sources.....

	<u>YES</u>	<u>NO</u>	
a. less than \$25,000?	1	2	(GO TO DM-14e)
DM14aIncome25Thousand			
b. less than \$20,000?	1	2	(DM-15)
DM14bIncome20Thousand			
c. less than \$15,000?	1	2	(DM-15)
DM14cIncome15Thousand			
d. less than \$10,000?	1 (DM-15)	2	(DM-15)
DM14dIncome10Thousand			
e. less than \$35,000?	1 (DM-15)	2	
DM14eIncome35Thousand			
f. less than \$50,000 (\$35,000 to less than \$50,000)?	1 (DM-15)	2	
DM14fIncome50Thousand			
g. less than \$75,000 (\$50,000 to less than \$75,000)?	1 (DM-15)	2	
DM14gIncome75Thousand			
h. less than \$100,000? (\$75,000 to less than \$100,000)?	1 (DM-15)	2	
DM14hIncome100Thousand			
i. less than 200,000? (\$100,000 to \$200,000)?	1 (DM-15)	2	
DM14iIncomeOver100Thousand			
j. \$200,000 or more?	1	2	
DM14jIncomeOver200Thousand			

DM-15. At the end of the month, how much money are you able to put aside?

DM15MoneySetAside

NOTHING	1
LESS THAN \$100	2
\$101 TO \$250	3
\$251 TO \$500	4
\$501 TO \$1,000	5
MORE THAN \$1000	6

DEBRIEFING QUESTIONS (DB)

You have completed all the questions on the survey. I just have a few additional questions for you about your participation in this study.

BOX DB-1

IF RESPONDENT CHOSE TO COMPLETE THE QUESTIONNAIRE BY PHONE, GO TO DB-08.

IF RESPONDENT WAS ASSIGNED TO THE TELEPHONE-ONLY CONDITION, GO TO DB-10.

IF THE RESPONDENT WAS ASSIGNED TO THE INTERNET-ONLY CONDITION, GO TO DB-02.

IF RESPONDENT CHOSE TO COMPLETE THE QUESTIONNAIRE BY INTERNET, CONTINUE.

CHOOSE THE INTERNET

DB-01. You were given a choice of whether to do this questionnaire over the phone or over the Internet. Why did you decide to do this survey over the Internet?

DB01WhyChoseInternet

DB-02. Did you have any difficulties accessing the survey?

DB02AccessDifficulties

- Yes..... 1
- No 2 (DB-04)

DB-03. What difficulties did you have?

DB03SpecifyDifficulties

DB-04. How satisfied were you with the speed of your connection to the survey? Would you say.....

DB04HowSatisfiedWithSpeed

- very satisfied, 1
- somewhat satisfied, 2
- somewhat dissatisfied, or 3
- very dissatisfied? 4

DB-05. Are you completing this survey all in one sitting, or did you take a break part-way through the survey to do something else?

DB05TookBreak

- I completed the survey all in one sitting 1
- I took a break part-way through the survey 2

DB-06. During the time that you have been completing this survey, were you also doing other things such as talking to someone, reading a newspaper, or caring for children?

DB06WhetherDistracted

- Yes..... 1
- No 2 (DB-10)

DB-07. What other things were you doing?
DB07Distractions

GO TO DB-10.

CHOSE TELEPHONE

DB-8. You were given a choice of whether to do this questionnaire over the phone or over the Internet. Why did you decide to do this survey over the telephone?
DB8WhyChoseTelephone

DB-9. Did you receive a letter or an e-mail with information about how to complete the survey on the Internet?
DB9RecievedLetter

- YES 1
- NO 2

ALL RESPONDETNS

DB-10. What do you think about the length of this survey? Would you say . . .
DB10LengthOfSurvey

- The survey was too short..... 1
- The survey was too long, or..... 2
- The survey was a good length..... 3

BOX DB-2
IF RESPONDENT IS NOT RECEIVING AN INCENTIVE, GO TO THE NEXT SECTION. OTHERWISE, CONTINUE.

DB-11. How likely is it that you would have participated in this survey if you were not receiving {FILL AMOUNT}? Would you say.....
DB11InfluenceOfIncentive

- very likely, 1
- somewhat likely,..... 2
- somewhat unlikely, or 3
- very unlikely? 4

CONTACT INFORMATION (CI)

BOX CI-1
IF RESPONDENT HAS NOT BEEN SELECTED FOR AN INCENTIVE, GO TO END STATEMENT 2.
IF RESPONDENT'S ADDRESS IS IN THE MANAGEMENT SYSTEM, FILL ADDRESS IN CI-01.

Thank you very much. We would like to send you a check for {FILL AMOUNT} as a thank you for your participation in this study.

CI-01. {I just need your mailing address, so that I can send you the check./I just want to confirm your address, so that I can send you the check. I have recorded that it is [FILL WITH STREET ADDRESS.]}

[UPDATE ADDRESS INFORMATION AS NECESSARY.]

STREET ADDRESS1
C11HHStreetAddress1 "C11 HH Street Address1"

DK..... (END STATEMENT2)
RF..... (END STATEMENT2)

STREET ADDRESS2
C11HHStreetAddress2 "C11 HH Street Address2"

CITY
C11HHCity "C11 HH City"

[PROGRAMMER: DISPLAY FULL STATE NAME AFTER INTERVIEWER ENTERS 2-DIGIT STATE ABBREVIATION.]

STATE C11HHState "C11 HH State"
C11HHZipCode ZIP CODE "C11 HH Zip Code"

END STATEMENT 2. Those are all of the questions that I have for you. Thank you for your time. If you have questions about cancer or want some information about cancer, you can call 1-800-4-CANCER or go to the National Cancer Institute's web site at: www.cancer.gov

ATTACHMENT 3a

Household Advance Letter



National Institutes of Health
Division of Cancer Control and Population Sciences
Health Communication and Informatics Research Branch
OMB # XXXXXXXX
Expiration Date: XX/XX/XXXX

Date

FRIEND RESIDING AT
«MAILADDR»
«MAILCITY», «MAILST» «MAILZIP»

Dear Friend:

Few things in life are as important as health. I am writing to encourage your household's participation in an important national survey sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health. The survey, known as the Health Information National Trends Survey, is authorized under 42 USC, Section 285a. The survey concerns what people know, believe and do about certain aspects of their health. The results of the study will help NCI's ongoing effort to promote good health and prevent disease.

Your household was selected at random for this nationwide survey. Westat, a research firm in Rockville, Maryland, is collecting data for this study for NCI. Sometime in the next month, a Westat interviewer will call your household.

Your participation is voluntary, but we would greatly appreciate your assistance. Be assured that there will be no penalties if you decide not to respond, either to the information collection as a whole, or to any particular question. The information you provide will be kept confidential and will not be disclosed in identifiable form to anyone but the researchers conducting this study or as provided by law.

Whether you are in good health or have health problems and whether or not you or anyone in your family has ever had cancer, your input and opinions are crucial to the success of this study. Your answers, combined with those of other survey respondents, will help the National Cancer Institute better serve the information needs of the American public. We hope that when you are contacted you will agree to help. Responding to the survey will take 20 to 30 minutes, depending on your answers.

We know that people receive many requests to be in surveys, and that your time is valuable. We have enclosed \$2 as a token of our appreciation for your participation in the study. Thank you in advance for your cooperation. If you have any questions about the study or you would like to go ahead and schedule your interview, you may call Westat at 1-888-XXX-XXXX.

Sincerely,

Brad W. Hesse, Ph.D.
HINTS Project Officer
Behavioral Research Program
National Cancer Institute



Some Frequently Asked Questions

What is the study about? What kind of questions will you be asking?

We will ask for your views and beliefs about cancer, and other health-related topics. We will also ask about your use of communication tools such as television, radio, and the Internet.

How did you get my (unlisted) phone number?

Your number was randomly selected from among all of the possible telephone numbers in the nation. It was selected using scientific sampling methods, so as to obtain a sample of people representative of the U.S. population. We do not use telephone directories to select telephone numbers. Your number was dialed at random by a computer, so if you have an unlisted number, that is why it was called. There has been no change in the listing status of your telephone number.

How did you get my address?

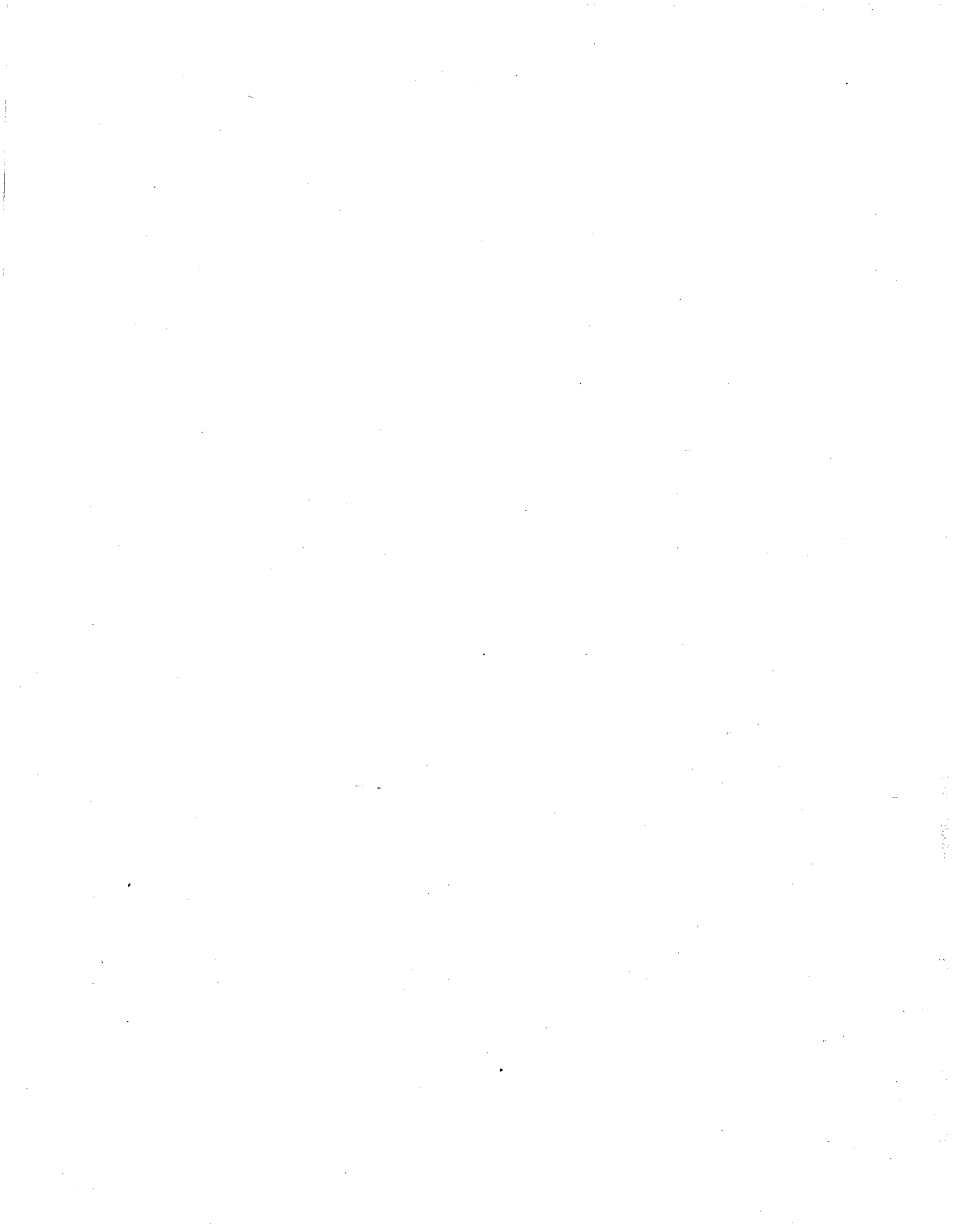
An independent organization matched a list of published addresses to the randomly selected list of telephone numbers. This letter was sent to addresses that were matched with a telephone number. All address information will be destroyed as soon as the study is completed.

Will you keep my information confidential?

Absolutely. All Westat employees working on a study are required by Federal law to protect the confidentiality of respondents. All of the answers you provide for the survey will be kept strictly anonymous. Moreover, individual responses to the study will never be published in reports. Answers will be combined and reported only as group totals or as part of overall statistical trends.

How long will the survey take?

First, there are a few questions to see which members of your household qualify for the study and which one will be selected to participate. This takes only 2 minutes. The remaining questions usually take 20 to 30 minutes.



ATTACHMENT 3b

Sampled Person Advance Letters



National Institutes of Health
Division of Cancer Control and Population Sciences
Health Communication and Informatics Research Branch
OMB # XXXXXXXX
Expiration Date: XX/XX/XXXX

Date

FRIEND RESIDING AT
«MAILADDR»
«MAILCITY», «MAILST» «MAILZIP»

Dear Friend:

Few things in life are as important as health. I am writing to encourage your participation in an important national survey sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health. The survey, known as the Health Information National Trends Survey, is authorized under 42 USC, Section 285a. The survey concerns what people know, believe and do about certain aspects of their health. The results of the study will help NCI's ongoing effort to promote good health and prevent disease.

You were selected at random for this nationwide survey. Westat, a research firm in Rockville, Maryland, is collecting data for this study for NCI. Sometime in the next month, a Westat interviewer will call you to conduct an interview.

Your participation is voluntary, but we would greatly appreciate your assistance. Be assured that there will be no penalties if you decide not to respond, either to the information collection as a whole, or to any particular question. The information you provide will be kept confidential and will not be disclosed in identifiable form to anyone but the researchers conducting this study or as provided by law.

Whether you are in good health or have health problems and whether or not you or anyone in your family has ever had cancer, your input and opinions are crucial to the success of this study. Your answers, combined with those of other survey respondents, will help the National Cancer Institute better serve the information needs of the American public. We hope that when you are contacted you will agree to help. Responding to the survey will take 20 to 30 minutes, depending on your answers.

We know that people receive many requests to be in surveys, and that your time is valuable. {As a token of our appreciation, we will provide you with (\$10/\$20) once we complete the interview.} Thank you in advance for your cooperation. If you have any questions about the study or you would like to schedule your interview, you may call Westat at 1-888-XXX-XXXX.

Sincerely,

Brad W. Hesse, Ph.D.
HINTS Project Officer
Behavioral Research Program
National Cancer Institute



National Institutes of Health
Division of Cancer Control and Population Sciences
Health Communication and Informatics Research Branch
OMB # XXXXXXXX
Expiration Date: XX/XX/XXXX

Date

FRIEND RESIDING AT
«MAILADDR»
«MAILCITY», «MAILST» «MAILZIP»

Dear Friend:

Few things in life are as important as health. I am writing to encourage your participation in an important national survey sponsored by the National Cancer Institute (NCI), part of the National Institutes of Health. The survey, known as the Health Information National Trends Survey, is authorized under 42 USC, Section 285a. The survey concerns what people know, believe and do about certain aspects of their health. The results of the study will help NCI's ongoing effort to promote good health and prevent disease.

You were selected at random for this nationwide survey. Westat, a research firm in Rockville, Maryland, is collecting data for this study for NCI. In order to access this internet survey, please go to www.XXXXXXX and enter your user name and password, noted below.

User name: XXXXXXXXX
Password: XXXXXX

Your participation is voluntary, but we would greatly appreciate your assistance. Be assured that there will be no penalties if you decide not to respond, either to the information collection as a whole, or to any particular question. The information you provide will be kept confidential and will not be disclosed in identifiable form to anyone but the researchers conducting this study or as provided by law.

Whether you are in good health or have health problems and whether or not you or anyone in your family has ever had cancer, your input and opinions are crucial to the success of this study. Your answers, combined with those of other survey respondents, will help the National Cancer Institute better serve the information needs of the American public. We hope that when you are contacted you will agree to help. Responding to the survey will take 20 to 30 minutes, depending on your answers.

We know that people receive many requests to be in surveys, and that your time is valuable. {As a token of our appreciation, we will provide you with (\$10/\$20) once we complete the interview.} Thank you in advance for your cooperation. If you have any questions about the study or problems access the internet survey, you may call Westat at 1-888-XXX-XXXX.

Sincerely,

Brad W. Hesse, Ph.D.
HINTS Project Officer
Behavioral Research Program
National Cancer Institute

ATTACHMENT 3c

Refusal Conversion Letters



National Institutes of Health
Division of Cancer Control and Population Sciences
Health Communication and Informatics Research Branch
OMB # XXXXX
Expiration Date: XX/XX/XXXX

Date

FRIEND RESIDING AT
«MAILADDR»
«MAILCITY», «MAILST» «MAILZIP»

Dear Resident:

Recently, a research interviewer called your household about a national study being conducted for the National Cancer Institute (NCI). The NCI is part of the Department of Health and Human Services and the National Institutes of Health. Perhaps the call came at a bad time.

We know your time is valuable, but your participation in the study is important to its success. To be accurate, the results of the survey need to be based on the real views and experiences of all the people we try to call. The large number of interviews that we have done is very encouraging, but improving the accuracy of results depends upon getting answers from you and others who have not yet responded.

Whether or not you or anyone in your family has ever had cancer, your input and opinions are crucial to the success of this study. Your answers, combined with those of other survey respondents, will help the National Cancer Institute improve the way it disseminates information about cancer prevention to people in the United States.

We have asked that a telephone interviewer contact you again so that you can still participate in this very important telephone interview. If we happen to call at an inconvenient time, please suggest a time that is better for you. If you would like to begin an interview at your own convenience or if you would like to schedule an appointment, please call Westat toll free at 888-XXX-XXXX.

More information about the study is available on the back of this letter. We hope you choose to be represented in this important health study.

Sincerely,

Brad W. Hesse, Ph.D.
HINTS II Project Officer
Behavioral Research Program
National Cancer Institute



National Institutes of Health
Division of Cancer Control and Population Sciences
Health Communication and Informatics Research Branch
OMB # XXXXX
Expiration Date: XX/XX/XXXX

Date

FRIEND RESIDING AT
«MAILADDR»
«MAILCITY», «MAILST» «MAILZIP»

Dear Friend:

Recently, a research interviewer called you about a national study being conducted for the National Cancer Institute (NCI). The NCI is part of the Department of Health and Human Services and the National Institutes of Health. Perhaps the call came at a bad time.

We know your time is valuable, but your participation in the study is important to its success. To be accurate, the results of the survey need to be based on the real views and experiences of all the people we try to call. The large number of interviews that we have done is very encouraging, but improving the accuracy of results depends upon getting answers from you and others who have not yet responded.

Whether or not you or anyone in your family has ever had cancer, your input and opinions are crucial to the success of this study. Your answers, combined with those of other survey respondents, will help the National Cancer Institute improve the way it disseminates information about cancer prevention to people in the United States.

We have asked that a telephone interviewer contact you again so that you can still participate in this very important telephone interview. If we happen to call at an inconvenient time, please suggest a time that is better for you. If you would like to begin an interview at your own convenience or if you would like to schedule an appointment, please call Westat toll free at 888-XXX-XXXX.

We know that your time is valuable. {As a token of our appreciation, we will provide you with (\$10/\$20) once we complete the interview.} We hope you choose to be represented in this important health study.

Sincerely,

Brad W. Hesse, Ph.D.
HINTS II Project Officer
Behavioral Research Program
National Cancer Institute



National Institutes of Health
 Division of Cancer Control and Population Sciences
 Health Communication and Informatics Research Branch
 OMB # XXXXX
 Expiration Date: XX/XX/XXXX

Date

FRIEND RESIDING AT
 «MAILADDR»
 «MAILCITY», «MAILST» «MAILZIP»

Dear Resident:

Recently, you received a letter from the National Cancer Institute (NCI) about completing an internet survey as part of a national study. The NCI is part of the Department of Health and Human Services and the National Institutes of Health.

We know your time is valuable, but your participation in the study is important to its success. To be accurate, the results of the survey need to be based on the real views and experiences of all the people we contact. The large number of interviews that we have done is very encouraging, but improving the accuracy of results depends upon getting answers from you and others who have not yet responded.

Whether or not you or anyone in your family has ever had cancer, your input and opinions are crucial to the success of this study. Your answers, combined with those of other survey respondents, will help the National Cancer Institute improve the way it disseminates information about cancer prevention to people in the United States.

Completing the survey is easy: just go to www.XXXXXX and enter your user name and password, noted below.

User name: XXXXXXXX
 Password: XXXXXX

If you have any problem accessing the internet survey, please feel free to call Westat toll free at 888-XXX-XXXX for assistance.

If you would prefer to complete this survey over the phone instead of the internet, we would be happy to accommodate you at whatever time is most convenient for you. Please call Westat toll free at 888-XXX-XXXX to let them know you would like to participate by telephone and to schedule an appointment for a time that would be convenient for you.

More information about the study is available on the back of this letter. We know that your time is valuable. {As a token of our appreciation, we will provide you with (\$10/\$20) once we complete the interview.} We hope you choose to be represented in this important health study.

Sincerely,

Brad W. Hesse, Ph.D.
 HINTS II Project Officer
 Behavioral Research Program
 National Cancer Institute

ATTACHMENT 4

Privacy Act System of Records Notice

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**STORAGE:**

Records are stored on paper forms in file folders and in electronic databases.

RETRIEVABILITY:

Records are retrieved by name, date of birth, type of medical staff membership, Institute/Center and licensing status.

SAFEGUARDS:

1. *Authorized Users:* Data on the computer network system is accessed by a password known only to authorized users who are NIH employees and contractor staff responsible for implementing the medical staff credentials data system. Access to information is thus limited to those with a need to know.

2. *Physical Safeguards:* Rooms where records are stored are locked when not in use. During regular business hours rooms are unlocked but entry is controlled by on-site personnel.

3. *Procedural and Technical Safeguards:* Access to files is strictly controlled by the system manager. Names and other identifying particulars are deleted when data from original records are encoded for analysis. Data stored in computers is accessed through a network system by use of a password known only to authorized users. All authorized users of personal information in connection with the performance of their jobs (see Authorized Users, above) protect information from public view and from unauthorized personnel entering an unsupervised office.

These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf: 45-13, and the HHS Automated Information Systems Security Program Handbook.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1B "Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 2300-293-4, "Medical Staffs' Credential Files," which allows inactive records to be transferred to the Federal Records Center at five year intervals and to be destroyed after thirty years. Refer to the NIH Manual Chapter for specific disposition instructions.

SYSTEM MANAGER(S) AND ADDRESS:

Chief, Credentialing Services Office, Clinical Center, Building 10, Room 1N204, 10 Center Drive, Bethesda, MD 20892-1192.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the System Manager at the above address. The requester must provide tangible proof of identity (e.g., driver's license). If no identification papers are available, the requester must verify his or her identity by providing either a notarization of the request or a written certification that the requester is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

RECORD ACCESS PROCEDURE:

Write to the System Manager specified above to attain access to records and provide the same information as that required under the Notification Procedures. Requesters should also reasonably specify the record contents being requested. Individuals may also request an accounting of disclosure of their records, if any.

CONTESTING RECORD PROCEDURE:

Contact the System Manager specified above and reasonably identify the record, specify the information to be contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely or irrelevant. The right to contest records is limited to information which is incomplete, irrelevant, incorrect, or untimely (obsolete).

RECORD SOURCE CATEGORIES:

Subject individual.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

09-25-0200

SYSTEM NAME:

Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD.

SECURITY CLASSIFICATION:

None.

SYSTEM LOCATION:

Records are located at NIH and Contractor research facilities which collect or provide research data for this

system. Contractors may include, but are not limited to: Research centers, clinics, hospitals, universities, medical schools, research institutions/foundations, national associations, commercial organizations, collaborating State and Federal Government agencies, and coordinating centers. A current list of sites, including the address of any Federal Records Center where records from this system may be stored, is available by writing to the appropriate Coordinator listed under Notification Procedure.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Adults and/or children who are the subjects of clinical, basic, or population-based research studies of the NIH. Individuals with disease. Individuals who are representative of the general population or of special groups including, but not limited to: normal controls, normal volunteers, family members and relatives; providers of services (e.g., health care and social work); health care professionals and educators, and demographic sub-groups as applicable, such as age, sex, ethnicity, race, occupation, geographic location; and groups exposed to real and/or hypothesized risks (e.g., exposure to biohazardous microbial agents).

CATEGORIES OF RECORDS IN THE SYSTEM:

The system contains data about individuals as relevant to a particular research study. Examples include, but are not limited to: name, study identification number, address, relevant telephone numbers, social security number (voluntary), driver's license number, date of birth, weight, height, sex, race; medical, psychological and dental information, laboratory and diagnostic testing results; registries; social, economic and demographic data; health services utilization; insurance and hospital cost data, employers, conditions of the work environment, exposure to hazardous substances/compounds; information pertaining to stored biologic specimens (including blood, urine, tissue and genetic materials), characteristics and activities of health care providers and educators and trainers (including *curricula vitae*); and associated correspondence.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

"Research and Investigation," "Appointment and Authority of the Directors of the National Research Institutes," "National Cancer Institute," "National Eye Institute," "National Heart, Lung and Blood Institute," "National Institute on Aging," "National

Institute on Alcohol Abuse and Alcoholism," "National Institute on Allergy and Infectious Diseases," "National Institute of Arthritis and Musculoskeletal and Skin Diseases," "National Institute of Child Health and Human Development," "National Institute on Deafness and Other Communication Disorders," "National Institute of Dental and Craniofacial Research," "National Institute of Diabetes, and Digestive and Kidney Diseases," "National Institute of Drug Abuse," "National Institute of Environmental Health Sciences," "National Institute of Mental Health," "National Institute of Neurological Disorders and Stroke," and the "National Human Genome Research Institute" of the Public Health Service Act. (42 U.S.C. 241, 242, 248, 281, 282, 284, 285a, 285b, 285c, 285d, 285e, 285f, 285g, 285h, 285i, 285j, 285l, 285m, 285n, 285o, 285p, 285q, 287, 287b, 287c, 289a, 289c, and 44 U.S.C. 3101.)

PURPOSE(S):

To document, track, monitor and evaluate NIH clinical, basic, and population-based research activities.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record may be disclosed for a research purpose, when the Department: (A) Has determined that the use or disclosure does not violate legal or policy limitations under which the record was provided, collected, or obtained; e.g., disclosure of alcohol or drug abuse patient records will be made only in accordance with the restrictions of confidentiality statutes and regulations 42 U.S.C. 241, 42 U.S.C. 290dd-2, 42 CFR part 2, and where applicable, no disclosures will be made inconsistent with an authorization of confidentiality under 42 U.S.C. 241 and 42 CFR part 2a; (B) has determined that the research purpose (1) cannot be reasonably accomplished unless the record is provided in individually identifiable form, and (2) warrants the risk to the privacy of the individual that additional exposure of the record might bring; (C) has required the recipient to (1) establish reasonable administrative, technical, and physical safeguards to prevent unauthorized use or disclosure of the record, (2) remove or destroy the information that identifies the individual at the earliest time at which removal or destruction can be accomplished consistent with the purpose of the research project, unless the recipient has presented adequate justification of a research or health nature for retaining such information,

and (3) make no further use or disclosure of the record except (a) in emergency circumstances affecting the health or safety of any individual, (b) for use in another research project, under these same conditions, and with written authorization of the Department, (c) for disclosure to a properly identified person for the purpose of an audit related to the research project, if information that would enable research subjects to be identified is removed or destroyed at the earliest opportunity consistent with the purpose of the audit, or (d) when required by law; and (D) has secured a written statement attesting to the recipient's understanding of, and willingness to abide by, these provisions.

2. Disclosure may be made to a Member of Congress or to a Congressional staff member in response to an inquiry of the Congressional office made at the written request of the constituent about whom the record is maintained.

3. The Department of Health and Human Services (HHS) may disclose information from this system of records to the Department of Justice when: (a) The agency or any component thereof; or (b) any employee of the agency in his or her official capacity where the Department of Justice has agreed to represent the employee; or (c) the United States Government, is a party to litigation or has an interest in such litigation, and by careful review, the agency determines that the records are both relevant and necessary to the litigation and the use of such records by the Department of Justice is, therefore, deemed by the agency to be for a purpose that is compatible with the purpose for which the agency collected the records.

4. Disclosure may be made to agency contractors, grantees, experts, consultants, collaborating researchers, or volunteers who have been engaged by the agency to assist in the performance of a service related to this system of records and who need to have access to the records in order to perform the activity. Recipients shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).

5. Information from this system may be disclosed to Federal agencies, State agencies (including the Motor Vehicle Administration and State vital statistics offices, private agencies, and other third parties (such as current or prior employers, acquaintances, relatives), when necessary to obtain information on morbidity and mortality experiences and to locate individuals for follow-up studies. Social security numbers, date of

birth and other identifiers may be disclosed: (1) To the National Center for Health Statistics to ascertain vital status through the National Death Index; (2) to the Health Care Financing Agency to ascertain morbidities; and (3) to the Social Security Administration to ascertain disabilities and/or location of participants. Social security numbers may also be given to other Federal agencies, and State and local agencies when necessary to locating individuals for participation in follow-up studies.

6. Medical information may be disclosed in identifiable form to tumor registries for maintenance of health statistics, e.g., for use in research studies.

7. PHS may inform the sexual and/or needle-sharing partner(s) of a subject individual who is infected with the human immunodeficiency virus (HIV) of their exposure to HIV, under the following circumstances: (1) The information has been obtained in the course of clinical activities at PHS facilities carried out by PHS personnel or contractors; (2) The PHS employee or contractor has made reasonable efforts to counsel and encourage the subject individual to provide the information to the individual's sexual or needle-sharing partner(s); (3) The PHS employee or contractor determines that the subject individual is unlikely to provide the information to the sexual or needle-sharing partner(s) or that the provision of such information cannot reasonably be verified; and (4) The notification of the partner(s) is made, whenever possible, by the subject individual's physician or by a professional counselor and shall follow standard counseling practices.

PHS may disclose information to State or local public health departments, to assist in the notification of the subject individual's sexual and/or needle-sharing partner(s), or in the verification that the subject individual has notified such sexual or needle-sharing partner(s).

8. Certain diseases and conditions, including infectious diseases, may be reported to appropriate representatives of State or Federal Government as required by State or Federal law.

9. Disclosure may be made to authorized organizations which provide health services to subject individuals or provide third-party reimbursement or fiscal intermediary functions, for the purpose of planning for or providing such services, billing or collecting third-party reimbursements.

10. The Secretary may disclose information to organizations deemed qualified to carry out quality assessment, medical audits or utilization reviews.

11. Disclosure may be made for the purpose of reporting child, elder or spousal abuse or neglect or any other type of abuse or neglect as required by State or Federal law.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records may be stored on index cards, file folders, computer tapes and disks (including optical disks), photography media, microfiche, microfilm, and audio and video tapes. For certain studies, factual data with study code numbers are stored on computer tape or disk, while the key to personal identifiers is stored separately, without factual data, in paper/computer files.

RETRIEVABILITY:

During data collection stages and follow-up, retrieval is by personal identifier (e.g., name, social security number, medical record or study identification number, etc.). During the data analysis stage, data are normally retrieved by the variables of interest (e.g., diagnosis, age, occupation).

SAFEGUARDS:

1. *Authorized Users:* Access to identifiers and to link files is strictly limited to the authorized personnel whose duties require such access. Procedures for determining authorized access to identified data are established as appropriate for each location. Personnel, including contractor personnel, who may be so authorized include those directly involved in data collection and in the design of research studies, e.g., interviewers and interviewer supervisors; project managers; and statisticians involved in designing sampling plans. Other one-time and special access by other employees is granted on a need-to-know basis as specifically authorized by the system manager. Researchers authorized to conduct research on biologic specimens will typically access the system through the use of encrypted identifiers sufficient to link individuals with records in such a manner that does not compromise confidentiality of the individual.

2. *Physical Safeguards:* Records are either stored in locked rooms during off-duty hours, locked file cabinets, and/or secured computer facilities. For certain studies, personal identifiers and link files are separated and stored in locked files. Computer data access is limited through the use of key words known only to authorized personnel.

3. *Procedural Safeguards:* Collection and maintenance of data is consistent

with legislation and regulations in the protection of human subjects, informed consent, confidentiality, and confidentiality specific to drug and alcohol abuse patients where these apply. When anonymous data is provided to research scientists for analysis, study numbers which can be matched to personal identifiers will be eliminated, scrambled, or replaced by the agency or contractor with random numbers which cannot be matched. Contractors who maintain records in this system are instructed to make no further disclosure of the records. Privacy Act requirements are specifically included in contracts for survey and research activities related to this system. The OHS project directors, contract officers, and project officers oversee compliance with these requirements. Personnel having access are trained in Privacy Act requirements. Depending upon the sensitivity of the information in the record, additional safeguard measures may be employed.

4. *Implementation Guidelines:* These practices are in compliance with the standards of Chapter 45-13 of the HHS General Administration Manual, "Safeguarding Records Contained in Systems of Records," supplementary Chapter PHS hf 45-13, and the HHS Automated Information Systems Security Program Handbook.

RETENTION AND DISPOSAL:

Records are retained and disposed of under the authority of the NIH Records Control Schedule contained in NIH Manual Chapter 1743, Appendix 1—"Keeping and Destroying Records" (HHS Records Management Manual, Appendix B-361), item 3000-G-3, which allows records to be kept as long as they are useful in scientific research. Collaborative Perinatal Project records are retained in accordance with item 3000-G-4, which does not allow records to be destroyed. Refer to the NIH Manual Chapter for specific conditions on disposal or retention instructions.

SYSTEM MANAGER(S) AND ADDRESS:

See Appendix I for a listing of current System Managers. This system is for use by all NIH Institutes and Centers.

NOTIFICATION PROCEDURE:

To determine if a record exists, write to the appropriate IC Privacy Act Coordinator listed below. In cases where the requester knows specifically which System Manager to contact, he or she may contact the System Manager directly (See Appendix I). Notification requests should include: individual's name; current address; date of birth; date, place and nature of participation

in specific research study; name of individual or organization administering the research study (if known); name or description of the research study (if known); address at the time of participation; and in specific cases, a notarized statement (some highly sensitive systems require two witnesses attesting to the individual's identity). A requester must verify his or her identity by providing either a notarization of the request or by submitting a written certification that the individual is who he or she claims to be and understands that the knowing and willful request for acquisition of a record pertaining to an individual under false pretenses is a criminal offense under the Act, subject to a five thousand dollar fine.

Individuals will be granted direct access to their medical records unless the System Manager determines that such access is likely to have an adverse effect (i.e., could cause harm) on the individual. In such cases when the System Manager has determined that the nature of the record information requires medical interpretation, the subject of the record shall be requested to designate, in writing, a responsible representative who will be willing to review the record and inform the subject individual of its contents at the representative's discretion. The representative may be a physician, other health professional, or other responsible individual. In this case, the medical/dental record will be sent to the designated representative. Individuals will be informed in writing if the record is sent to the representative. This same procedure will apply in cases where a parent or guardian requests notification of, or access to, a child's or incompetent person's medical record. The parent or guardian must also verify (provide adequate documentation) their relationship to the child or incompetent person as well as his or her own identity to prove their relationship.

If the requester does not know which Institute or Center Privacy Act Coordinator to contact for notification purposes, he or she may contact directly the NIH Privacy Act Officer at the following address: NIH Privacy Act Officer, Office of Management Assessment, 6011 Executive Blvd., Room 601L, Rockville, MD 20852.

NIH Privacy Act Coordinators

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, Clinical Center (CC), Building 10, Room 1N208, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Center for Complementary and Alternative Medicine (NCCAM), Building 31, Room 2B11, 31 Center Drive, Bethesda, MD 20892-2182.

Privacy Act Coordinator, National Cancer Institute (NCI), Building 31, Room 10A34, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Center on Minority Health and Health Disparities (NCMHD), Democracy Plaza II, Room 800, 6707 Democracy Boulevard, Bethesda, MD 20892-5465.

Privacy Act Coordinator, National Center for Research Resources (NCRR), Rockledge I, Room 5140, 6705 Rockledge Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Eye Institute (NEI), Building 31, Room 6A32, 31 Center Drive, Bethesda, MD 20892-2510.

Privacy Act Coordinator, National Human Genome Research Institute (NHGRI), Building 10, 3C710, 10 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Heart, Lung, and Blood Institute (NHLBI), Building 31, Room 5A33, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute on Aging (NIA), Gateway Building 31, Room 2C234, 7201 Wisconsin Avenue, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute on Alcohol Abuse and Alcoholism (NIAAA), Willco Building, Room 400, 6000 Executive Boulevard, Bethesda, MD 20892-7003.

Privacy Act Coordinator, National Institute of Allergy and Infectious Diseases (NIAID), 6700-B Rockledge Drive, Room 2143, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), Natcher Building, Room 5AS49, 45 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Biomedical Imaging and Bioengineering (NIBIB), Building 31, Room 1B37, 31 Center Drive, Bethesda, MD 20892-2077.

Privacy Act Coordinator, National Institute of Child Health and Human Development (NICHD), Building 31, Room 2A11, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, Office of Extramural Affairs, National Institute on Drug Abuse (NIDA), Neuroscience Center, 6001 Executive Boulevard, Room 3158, Bethesda, MD 20892-9547.

Privacy Act Coordinator, National Institute on Deafness and Other Communication Disorders (NIDCD),

Building 31, Room 3C02, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Dental and Craniofacial Research (NIDCR), Natcher Building, Room 4AS25, 45 Center Drive, Bethesda, MD 20892-6401.

Privacy Act Coordinator, National Institute of Diabetes and Digestive and Kidney Disease (NIDDK), Building 31, Room 9A47, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Environmental Health Sciences (NIEHS), PO Box 12233, Research Triangle Park, NC 27709.

Privacy Act Coordinator, National Institute of General Medical Sciences (NIGMS), Natcher Building, Room 2AN32, 45 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Mental Health (NIMH), Neuroscience Center, 6001 Executive Boulevard, Room 8102, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Neurological Disorders and Stroke (NINDS), Building 31, Room 8A33, 31 Center Drive, Bethesda, MD 20892.

Privacy Act Coordinator, National Institute of Nursing Research (NINR), Rockledge II, Room 710, 6701 Rockledge Drive, Bethesda, MD 20892.

RECORD ACCESS PROCEDURE:

Same as Notification Procedures. Requesters should reasonably specify the record contents being sought. An individual may also request an accounting of disclosures of his/her record, if any.

CONTESTING RECORD PROCEDURE:

Contact the appropriate official at the address specified under Notification Procedure, and reasonably identify the record, specify the information being contested, and state corrective action sought, with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant.

RECORD SOURCE CATEGORIES:

The system contains information obtained directly from the subject individual by interview (face-to-face or telephone), written questionnaire, or by other tests, recording devices or observations, consistent with legislation and regulation regarding informed consent and protection of human subjects. Information is also obtained from other sources, including but not limited to: referring medical physicians, mental health/alcohol/drug abuse or other health care providers; hospitals; organizations providing biological

specimens; relatives; guardians; schools; and clinical medical research records.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

Appendix I: System Manager(s) and Address(es)

Associate Director for Disease Prevention, Office of the Director (OD), Building 1, Room 260, 1 Center Drive, Bethesda, MD 20892.

Computer Systems Analyst, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 344, 6130 Executive Boulevard, Bethesda, MD 20892.

American Burkitt's Lymphoma Registry, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Suite 434, 6130 Executive Boulevard, Bethesda, MD 20892.

Chief, Genetic Epidemiology Branch, Division of Cancer Epidemiology and Genetics, National Cancer Institute (NCI), Executive Plaza South, Room 7122, 6120 Executive Boulevard, Bethesda, MD 20892-7236.

Program Director, Research Resources, Biological Carcinogenesis Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 540, 6130 Executive Boulevard, Bethesda, MD 20892.

Chief, Environmental Epidemiology Branch, Division of Cancer Etiology, National Cancer Institute (NCI), Executive Plaza North, Room 443, 6130 Executive Boulevard, Bethesda, MD 20892.

Associate Director, Surveillance Program, Division of Cancer Prevention, National Cancer Institute (NCI), Executive Plaza North, Room 343K, 6130 Executive Boulevard, Bethesda, MD 20892.

Head, Biostatistics and Data Management Section, Center for Cancer Research, National Cancer Institute (NCI), Building 6116, Room 702, 6116 Executive Boulevard, Bethesda, MD 20892.

Chief, Clinical Research Branch, Center for Cancer Research, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), 501 W. 7th Street, Room 3, Frederick, MD 21702.

Deputy Branch Chief, Navy Hospital, NCI-Naval Medical Oncology Branch, Center for Cancer Research, National Cancer Institute (NCI), Building 8, Room 5101, Bethesda, MD 20814.

Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of Cancer Treatment and Diagnosis, National Cancer Institute (NCI), Executive Plaza North, Room 804, 6130 Executive Boulevard, Bethesda, MD 20892.

Director, Extramural Clinical Studies, Frederick Cancer Research and Development Center, National Cancer Institute (NCI), Fort Detrick, Frederick, MD 21702.

Clinical Operations Manager, National Eye Institute (NEI), Building 10, Room 10S224, 10 Center Drive, Bethesda, MD 20892.

Director, Division of Biometry and Epidemiology, National Eye Institute (NEI), Building 31, Room 6A52, 31 Center Drive, Bethesda, MD 20892.

ATTACHMENT 5

60 Day Federal Register Notice

guidance document entitled "Pre-market Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Chiu S. Lin, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8913.

SUPPLEMENTARY INFORMATION:

I. Background

In the *Federal Register* of July 30, 1999 (64 FR 41744), FDA announced the availability of a draft guidance for comment entitled "Medical Glove Guidance Manual." (See <http://www.fda.gov/cdrh/dsma/135.html> for the draft guidance.) Elsewhere in the same issue of the *Federal Register* (64 FR 41710), FDA proposed that the 1999 draft guidance serve as a special control for class II gloves. However, chapter 4 of the 1999 draft guidance contained a section that discussed PMAs for absorbable powder for lubricating surgeon's gloves. Because the section discussing PMAs for absorbable powder is not relevant to class II gloves, FDA is removing this section and issuing it as a separate guidance document. FDA did not receive any comments on this section of the 1999 draft guidance. Because the recommendations in this section were available in draft form for comment, FDA is issuing this guidance as a final document. As with any guidance, however, you may submit comments at any time.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on PMAs for

absorbable powder for lubricating a surgeon's glove. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "Pre-market Approval Applications (PMA) for Absorbable Powder for Lubricating a Surgeon's Glove" by fax machine, call the Center for Devices and Radiological Health (CDRH) Facts-On-Demand system at 800-899-0381, or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1230) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, *Federal Register* reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 USC 3501-3520). The collections of information addressed in the guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket approval applications (21 CFR part 814, OMB control number 0910-0231). The labeling provisions addressed in the guidance have been approved by OMB under the PRA, OMB control number 0910-0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), written or electronic comments regarding the guidance at any time. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 30, 2004.

Beverly Chernaik Rothstein,
Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

[FR Doc. 04-8306 Filed 4-12-04; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Data Collection; Comment Request Health Information National Trends Survey (HINTS) II

SUMMARY: In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Health Information National Trends Survey (HINTS) II. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The Health Information National Trends Survey (HINTS) is a biennial survey designed to provide nationally representative, population-based data on health information for the United States. The NCI funded HINTS to assist in its effort to (1) encourage programmatic and interdisciplinary approaches to cancer communication research, and (2) accelerate development of innovative health communication models, theories, and research strategies in cancer prevention, control, and care. HINTS II, scheduled to commence in early 2005, will preserve the methodological integrity of the first cycle of HINTS by using the telephone as the primary mode of data collection as well as

retaining approximately 50% of the questionnaire content. In addition, HINTS II will experiment with alternative modes of data collection (i.e., the Internet). Data will be used (1) to understand individuals' sources of and access to cancer-related information; (2) to measure progress in improving cancer knowledge and communication to the general public; (3) to develop appropriate messages for the public

about cancer prevention, detection, diagnosis, treatment, and survivorship; and (4) to identify research gaps and guide decisions about NCI's research efforts in health promotion and health communication. *Frequency of response:* One-time. *Affected public:* Individuals. *Type of Respondents:* U.S. Adults, Pilot Survey, Screeners and Interview. The annual reporting burden is as follows: *Estimated Number of Respondents:*

10,389; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 37; and *Estimated Total Annual Burden Hours Requested:* 3,836. The annualized cost to respondents is estimated at \$38,360. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Type of respondent	Estimated number of respondents	Frequency of response	Average hours per response	Annual hour burden
Pilot Survey	150	1	4167	63
HINTS II Screener	10,239	1	.0833	854
HINTS II Interview*	7,004	1	4167	2,919
Totals				3,836

*HINTS II interview respondents are a subset of the screener respondents (N = 10,389).

Request For Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proposed performance of the functions of the agency, including whether the information shall have practical utility; (2) The accuracy of the estimate of the burden of the proposed collection of information including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. **FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Bradford W. Hesse, Ph.D., Project Officer, National Cancer Institute, NIH, EPN 4068, 6130 Executive Boulevard MSC 7365, Bethesda, Maryland 20892-7365, or call non-toll-free number (301) 594-9904, or FAX your request to (301) 480-2198, or E-mail your request, including your address, to hessab@mail.nih.gov.

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of this notice.

Dated: April 1, 2004.

Rachelle Ragland-Greene,
OMB Clearance Liaison, National Cancel
Institute, National Institutes of Health.
[FR Doc. 04-8270 Filed 4-12-04; 8:45 am]
BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.
ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

ADDRESSES: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301/496-7057; fax: 301/402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Query Tool for Accurate Protein Identification

Rodney L. Levine (NHLBI)
U.S. Patent Application No. 10/446,865
filed 29 May 2003 (DHHS Reference
No. E-306-2002/0-US-01)

Licensing Contact: Michael
Shmilovich; 301/435-5019;
shmilovm@mail.nih.gov.

PHS seeks a commercial developer for the following software database query tool: A data-mining tool (software based query generator) that provides a script that identifies an isolated protein by using physical properties of the protein and submitting the query into a protein database (e.g., SWISS-PROT). The inventors identified that by combining an accurate determination of the ratio of at least one amino acid per molecule and at least one physical parameter of the protein; an accurate and unique match can be made by the query results. Parameters include the ratios of amino acids to others (e.g., C/F, W/C, C/Y etc.), the molecular weight, the ratio of positively to negatively charged moieties, and/or the isoelectric point.

Bromotyrosine-Derived Inhibitors of Mycothiol-S-Conjugate Amidase

Carole A. Bewley *et al.* (NIDDK)

U.S. Provisional Application No. 60/395,219 filed 10 Jul 2002 (DHHS Reference No. E-196-2002/0-US-01); PCT Application No. PCT/US03/21456 filed 09 Jul 2003, which published as WO 04/004659 on 15 Jan 2004 (DHHS Reference No. E-196-2002/0-PCT-02)

Licensing Contact: Michael Ambrose;
301/594-6565; ambrosem@mail.nih.gov.

Mycobacterium tuberculosis has reemerged as a leading cause of death by an infectious agent, especially among populations that are immunocompromised. With this increase in the rate of infection there has also been an increase in the number of drug resistant strains, making treatment of such infections more difficult. As such, the development of new antituberculars with novel modes

ATTACHMENT 6

IRB Exemption Memo

OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN SUBJECTS

FAX: 301-480-2198
To: Hesse, Bradford
NCI
EPN 4068

OHSR #: 2684

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The Health Information National Trends Survey (HINTS) is a biennial telephone survey sponsored by the National Cancer Institute to assess the public's awareness of cancer prevention messages.

Original Request Received in OHSR on: 5/11/2004

Responsible NIH Research Investigator(s): Bradford Hesse, PhD NCI

OHSR review of your request dated Tue, May 11, 2004 has determined that:

- Federal regulations for the protection of human subjects do not apply to above named activity. No further action is necessary.
- The activity is designated **EXEMPT**, and has been entered in the OHSR database. **PLEASE NOTIFY OHSR OF ANY SIGNIFICANT CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.**
- NOT EXEMPT.** OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.
- Other

Note:

Charlotte S. Holder
Alan L. Sandler, D.D.S.

Director, OHSR

Signature

Title

5/21/04

Date

Domestic/International:

Domestic

Human Subjects Data Yes

Biologic Material:

OHSR Use Only

1 2 3 4 5 6



MEMORANDUM

TO: Holly Schiffrin
Project Director

FROM: Thomas W. McKenna *Thomas W. McKenna*
Chairman, Institutional Review Board

SUBJECT: IRB Review and Approval
Health Information National Trends Survey II
Contract N02-PC-3523 Project 7845
FWA 5551

April 8, 2004

As Chairman of the Westat Institutional Review Board, I have reviewed the materials submitted for the following: Health Information National Trends Survey II, Contract N02-PC-3523, Project 7845. Westat's Institutional Review Board (IRB) reviews all studies involving human research before activities may begin under 45 CFR pt 46.

The study is a national probability survey of adult respondents sampled from the general U.S. household population. The survey will focus on the extent that the general population understands cancer prevention messages, to enable NCI to develop more effective educational programs. Respondents will be asked questions about their health, health-related risk behaviors, medical conditions and treatment, and alcohol consumption. Respondents' names and addresses will be collected for purposes of mailing incentive payments; however, the risk to respondents from disclosure of this information may be considered minimal risk.

The regulations exempt research involving the use of survey or interview procedures without identifying information. 45 CFR §46.101(b)(2). Information collected in this survey is not sensitive, and no risks to subjects are anticipated.

I am therefore granting permission to begin performance under the contract. You must inform the Office of Research Administration if the design or content of the above study changes, to ensure that the study remains exempt from IRB approval. Additionally, you are responsible for notifying the ORA as soon as possible if you encounter any injuries or problems relating to human subjects.

cc: C. Maffeo



ATTACHMENT 7a

Westat Confidentiality Agreement

WESTAT

EMPLOYEE OR CONTRACTOR'S ASSURANCE OF CONFIDENTIALITY OF SURVEY DATA

Statement of Policy

Westat is firmly committed to the principle that the confidentiality of individual data obtained through Westat surveys must be protected. This principle holds whether or not any specific guarantee of confidentiality was given at time of interview (or self-response), or whether or not there are specific contractual obligations to the client. When guarantees have been given or contractual obligations regarding confidentiality have been entered into, they may impose additional requirements which are to be adhered to strictly.

Procedures for Maintaining Confidentiality

1. All Westat employees and field workers shall sign this assurance of confidentiality. This assurance may be superseded by another assurance for a particular project.
2. Field workers shall keep completely confidential the names of respondents, all information or opinions collected in the course of interviews, and any information about respondents learned incidentally during field work. Field workers shall exercise reasonable caution to prevent access by others to survey data in their possession.
3. Unless specifically instructed otherwise for a particular project, an employee or field worker, upon encountering a respondent or information pertaining to a respondent that s/he knows personally, shall immediately terminate the activity and contact her/his supervisor for instructions.
4. Survey data containing personal identifiers in Westat offices shall be kept in a locked container or a locked room when not being used each working day in routine survey activities. Reasonable caution shall be exercised in limiting access to survey data to only those persons who are working on the specific project and who have been instructed in the applicable confidentiality requirements for that project.
Where survey data have been determined to be particularly sensitive by the Corporate Officer in charge of the project or the President of Westat, such survey data shall be kept in locked containers or in a locked room except when actually being used and attended by a staff member who has signed this pledge.
5. Ordinarily, serial numbers shall be assigned to respondents prior to creating a machine-processible record and identifiers such as name, address, and Social Security number shall not, ordinarily, be a part of the machine record. When identifiers are part of the machine data record, Westat's Manager of Data Processing shall be responsible for determining adequate confidentiality measures in consultation with the project director. When a separate file is set up containing identifiers or linkage information which could be used to identify data records, this separate file shall be kept locked up when not actually being used each day in routine survey activities.
6. When records with identifiers are to be transmitted to another party, such as for keypunching or key taping, the other party shall be informed of these procedures and shall sign an Assurance of Confidentiality form.
7. Each project director shall be responsible for ensuring that all personnel and contractors involved in handling survey data on a project are instructed in these procedures throughout the period of survey performance. When there are specific contractual obligations to the client regarding confidentiality, the project director shall develop additional procedures to comply with these obligations and shall instruct field staff, clerical staff, consultants, and any other persons who work on the project in these additional procedures. At the end of the period of survey performance, the project director shall arrange for proper storage or disposition of survey data including any particular contractual requirements for storage or disposition. When required to turn over survey data to our clients, we must provide proper safeguards to ensure confidentiality up to the time of delivery.
8. Project directors shall ensure that survey practices adhere to the provisions of the U.S. Privacy Act of 1974 with regard to surveys of individuals for the Federal Government. Project directors must ensure that procedures are established in each survey to inform each respondent of the authority for the survey, the purpose and use of the survey, the voluntary nature of the survey (where applicable) and the effects on the respondents, if any, of not responding.

PLEDGE

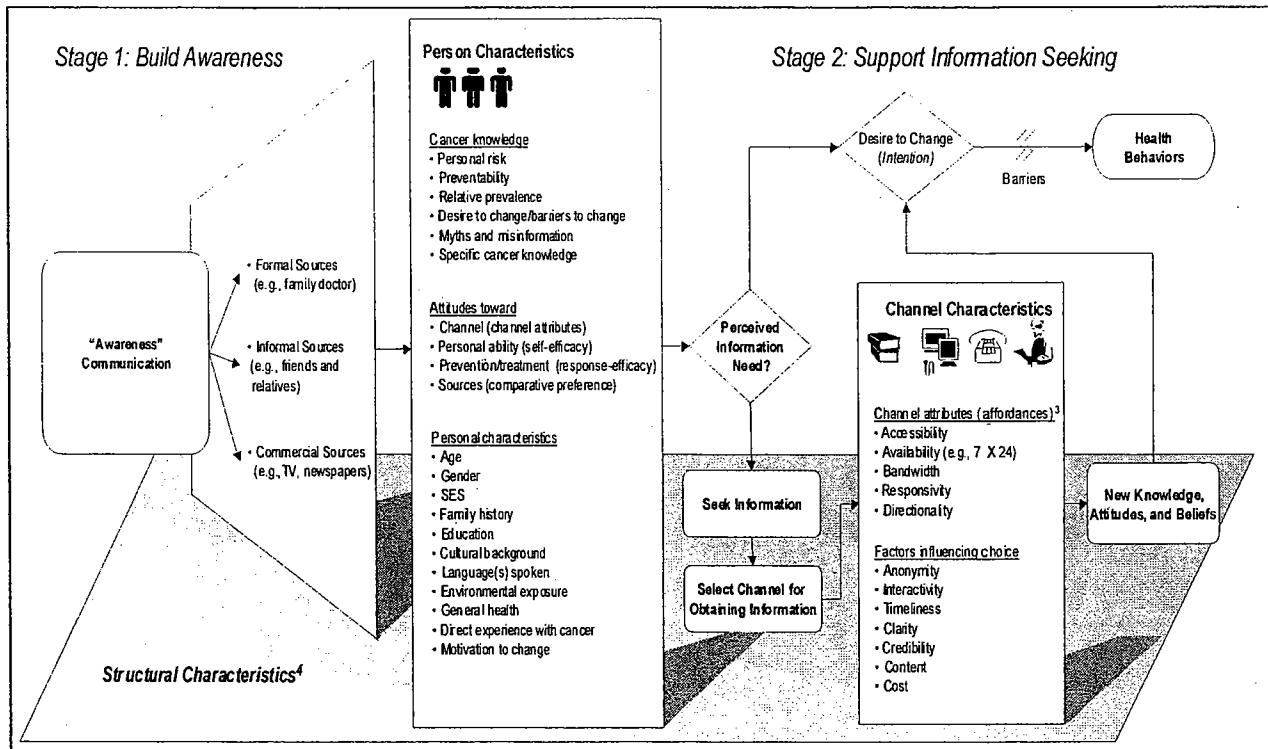
I hereby certify that I have carefully read and will cooperate fully with the above procedures. I will keep completely confidential all information arising from surveys concerning individual respondents to which I gain access. I will not discuss, disclose, disseminate, or provide access to survey data and identifiers except as authorized by Westat. In addition, I will comply with any additional procedures established by Westat for a particular contract. I will devote my best efforts to ensure that there is compliance with the required procedures by personnel whom I supervise. I understand that violation of this pledge is sufficient grounds for disciplinary action, including dismissal. I also understand that violation of the privacy rights of individuals through such unauthorized discussion, disclosure, dissemination, or access may make me subject to criminal or civil penalties. I give my personal pledge that I shall abide by this assurance of confidentiality.

XXXXXXXXXXXXXXXXXXXXXXXXXXXX

Signature

ATTACHMENT 7b

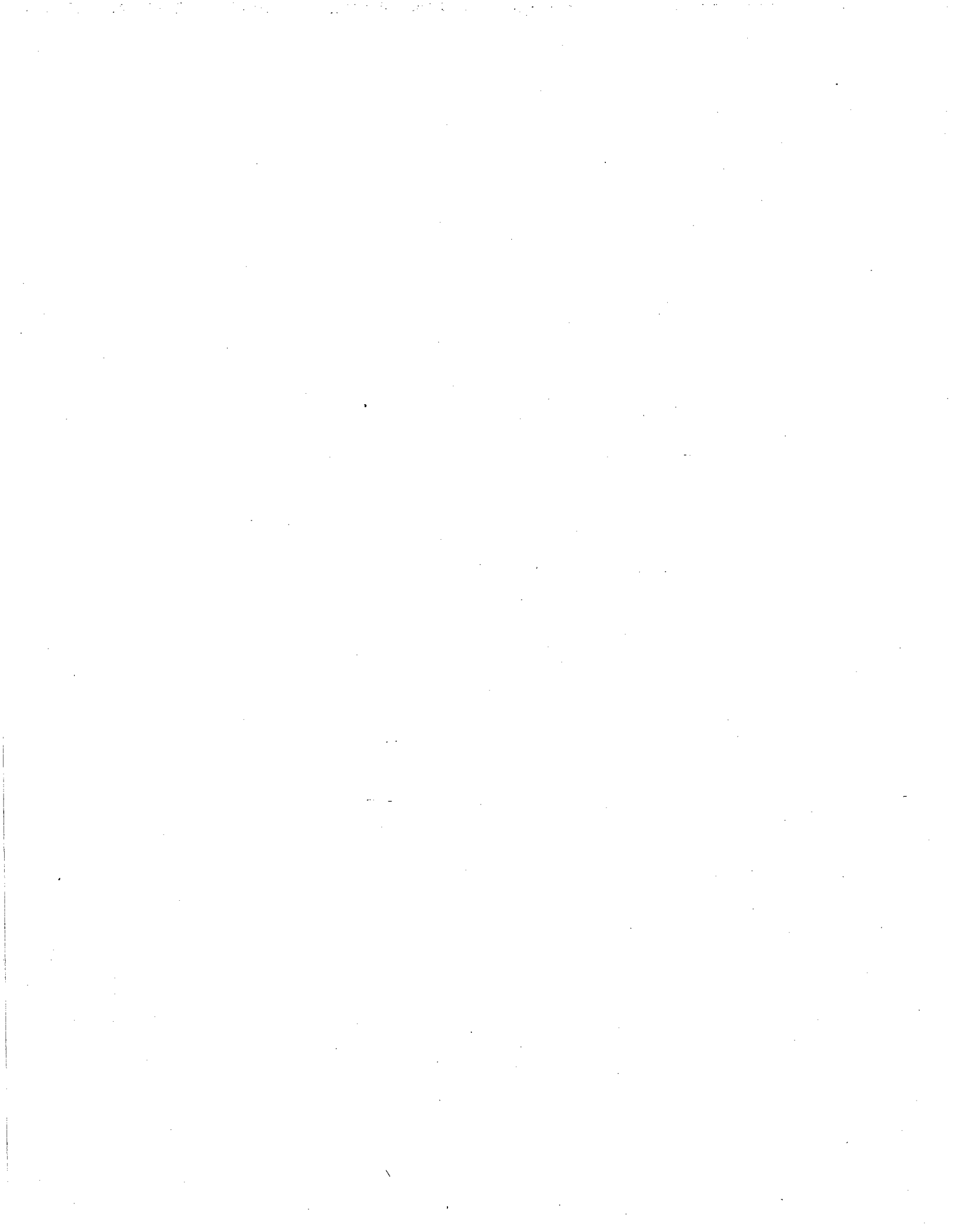
Theoretical Framework



HINTS Framework. Derived from extant theory in cancer communication and the behavioral sciences, the HINTS framework served as a guide to item development.

ATTACHMENT 7c

Expected Response Rates in Wave I



EXPECTED DISTRIBUTION OF TELEPHONE NUMBERS IN WAVE 1

We are carrying out a randomized experiment in Wave 1 of HINTS II, randomly assigning one-third of the telephone numbers to a telephone-interview-only branch, one-third of the numbers to a web-survey-only branch, and one-third of the numbers to a telephone-Internet respondent choice branch. Figures A-1, A-2, and A-3 show our expectations as to the distribution of respondents and nonrespondents in the various relevant subgroups of interest.

A very important dichotomization is between households which have Internet access, and households which do not have Internet access. The most recent Current Population Survey Computer Use and Internet Supplement (September 2001) indicates that roughly 60 percent of U.S. households have Internet access. The percentage is probably increasing, and will be larger in 2005, but we will use the 60 percent figure (this will be conservative with regard to estimating expected Internet interviews). For the Internet-only group, we will ask all of the Internet-access households to do the interview via Internet. For the telephone-Internet respondent-choice group, we will give them a choice to do the interview by Internet or by telephone. For the telephone-only group, we will ask all households to do the interview by telephone. Households without Internet access will all do the interviews by telephone (whatever their assigned mode branch).

A second dichotomization within the households with Internet access is households which give us access information (e.g., their email address). Without this access information, we will be obliged to ask them to log on to our web site themselves to complete the Internet interview. We expect 70 percent of Internet-access households to give us Internet access information, which will give us the chance to email to them follow-up prompts.

Figure A-1 presents our expectations as to the telephone-only branch. The breakout into households with and without Internet access (60% in the former group and 40% in the latter group) is not directly relevant to the fielding of the telephone-only branch, but is relevant to making comparisons between the telephone-only branch and the two Internet branches. Any mode comparison of telephone interview vs. Internet interviews is best restricted to households with Internet access, as households without Internet access may be a different population, and there can be no Internet interviews in these households. We will be asking all of the households (in all branches) whether or not they have Internet access, for the purpose of this necessary subgrouping for mode comparisons.

We assume an overall 71 percent response rate for telephone interviews in the telephone-only branch, expecting a 71 percent response rate for the non-Internet-access households, a 75 percent response rate for the Internet-access households which give access information, and a 61.7 percent response rate for the Internet-access households which do not give access information. A difference in the response rates for the two Internet-access household groups is likely, as households willing to give us Internet access information are certainly more likely to be cooperative for the telephone interview than the complement group, though we don't know to what degree. The 75 percent vs. 61.7 percent difference is our assumed difference (note that this averages to 71%: the overall assumed rate, averaging over the assumed 70 percent in the access-providing group and the 30 percent in the complement group). Note that we plan to invite final refusals to complete the survey by Internet. We expect a small percentage will cooperate. This is not reflected in Figure A-1.

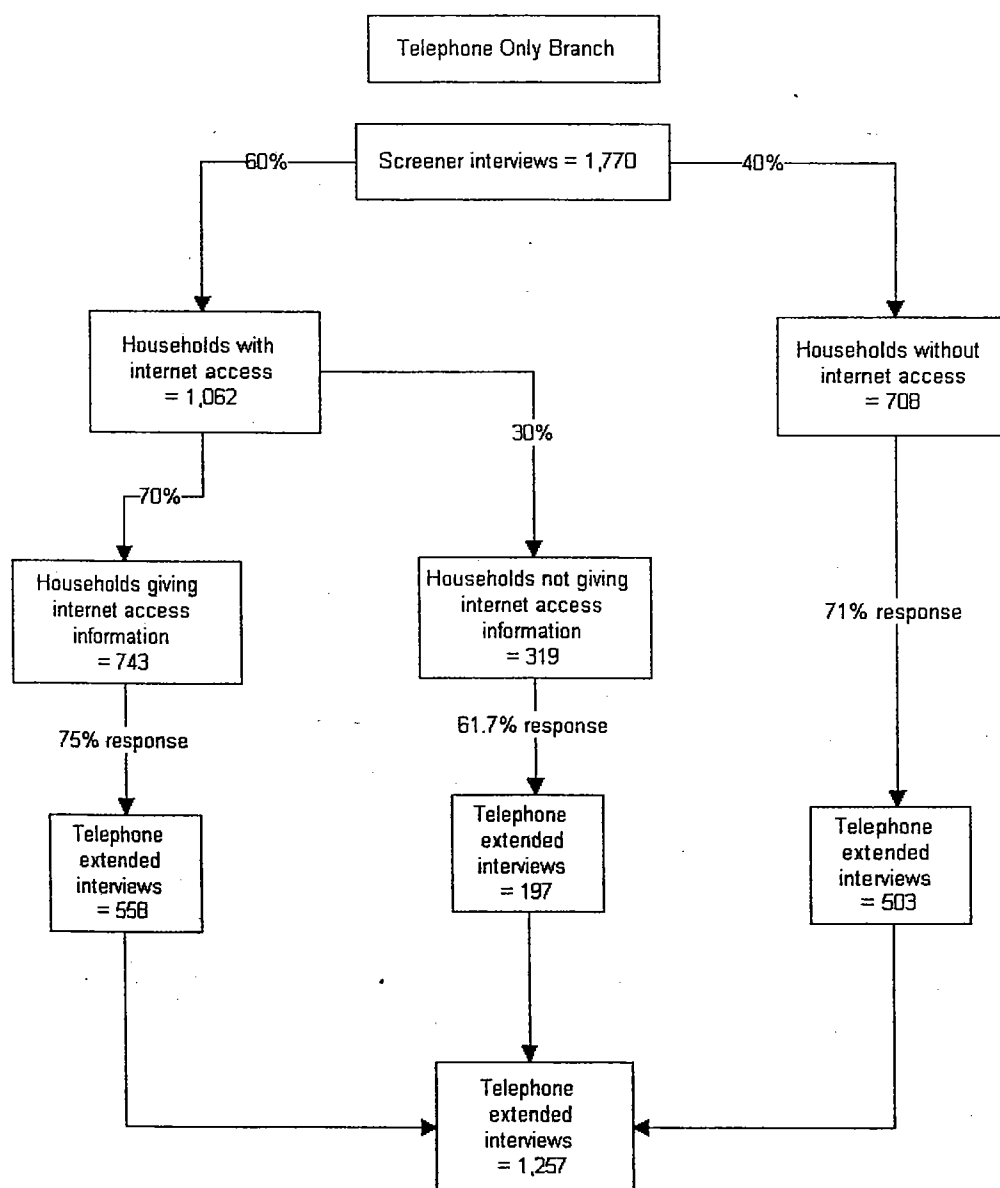


Figure A-1. Telephone-only branch

Figure A-2 provides our expected breakdown for the Internet-only branch. The households without Internet access have an identical result as for the telephone-only branch (they are all interviewed by telephone, with an expected 71% response rate). The households with Internet access split into those giving Internet access information (assumed 70%) and those not giving Internet access information (30%). For those households not giving Internet access information, we will request that they log in themselves to our web site and complete the interview. We expect only a small proportion (15%) to do this. Of those who do give us access information, we expect a 35 percent response rate for a final Internet interview.

We will also follow up any of those who do not complete an Internet interview by attempting to complete a telephone interview. We expect to pick up 22 percent of the access-providing group by followup telephone interview, and 35 percent of the non-access-providing group (for a total response rate Internet or telephone of 57 percent for the access-providing households and 50 percent for the non-access-providing households).

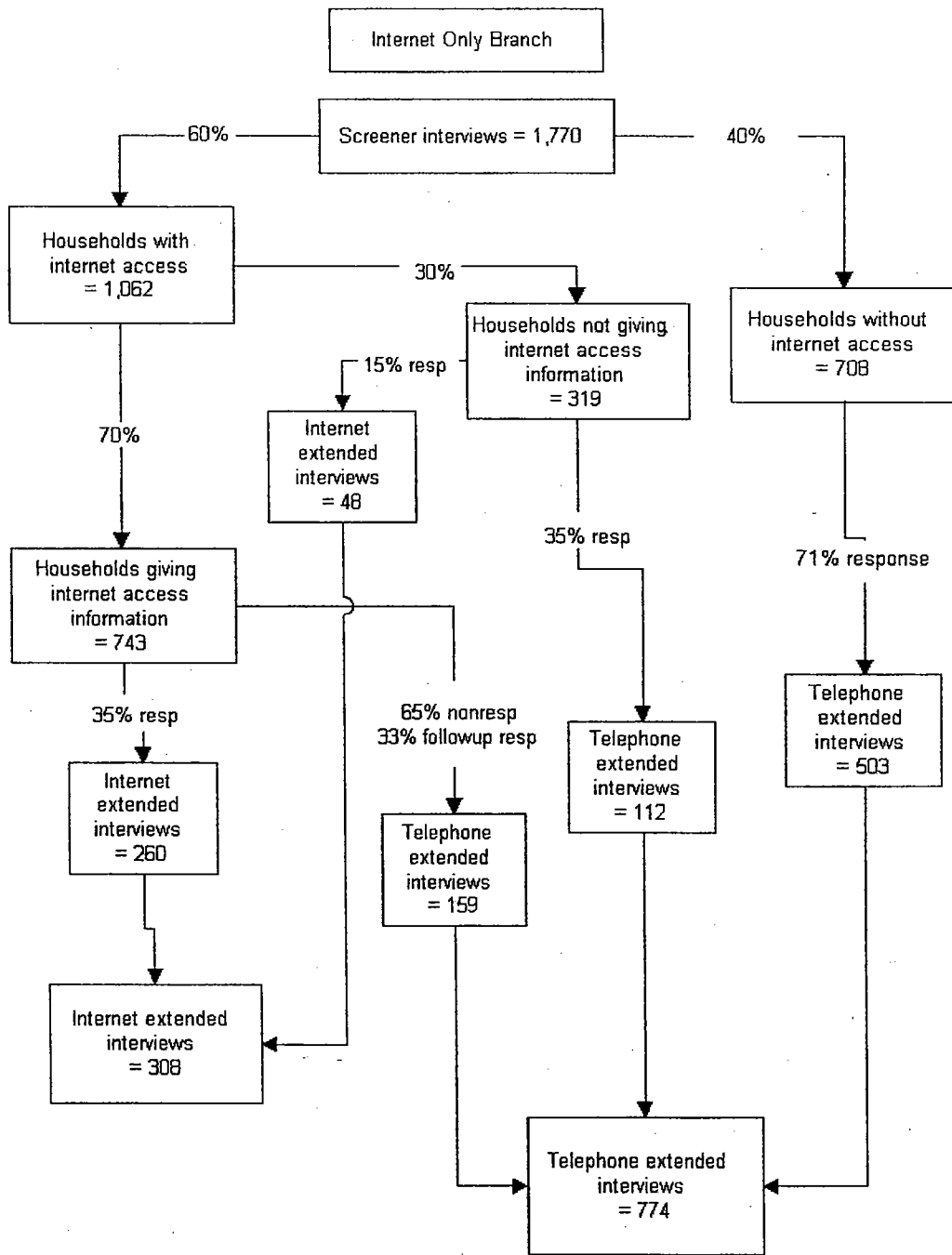


Figure A-2. Internet-only branch

Figure A-3 provides the expected breakdown for the telephone-Internet respondent choice branch. The households without Internet access are identical to those of the telephone-only or Internet-only branches: they are recruited to do telephone interviews with the same expected recruitment rates. The households with Internet access are asked whether or not they wish to do the interview by telephone or by Internet. We expect 50 percent to choose Internet, and 50 percent telephone (given the lack of available data, these percentages are only rough approximations).

The next dichotomization is by whether the households provide Internet access information (the 'access-provider' group and the 'nonaccess-provider' group). We expect 70 percent of Internet access households to be access providers (as assumed in Figures A-1 and A-2). In this case, though, we expect a much larger percentage of those who choose the Internet as their interview mode to also be access providers (85%). We expect only 55 percent of the telephone preference group to be access providers. The remaining branches and percentages in Figure A-3 are self-explanatory, mirroring similar calculations for the telephone-only and Internet-only groups.

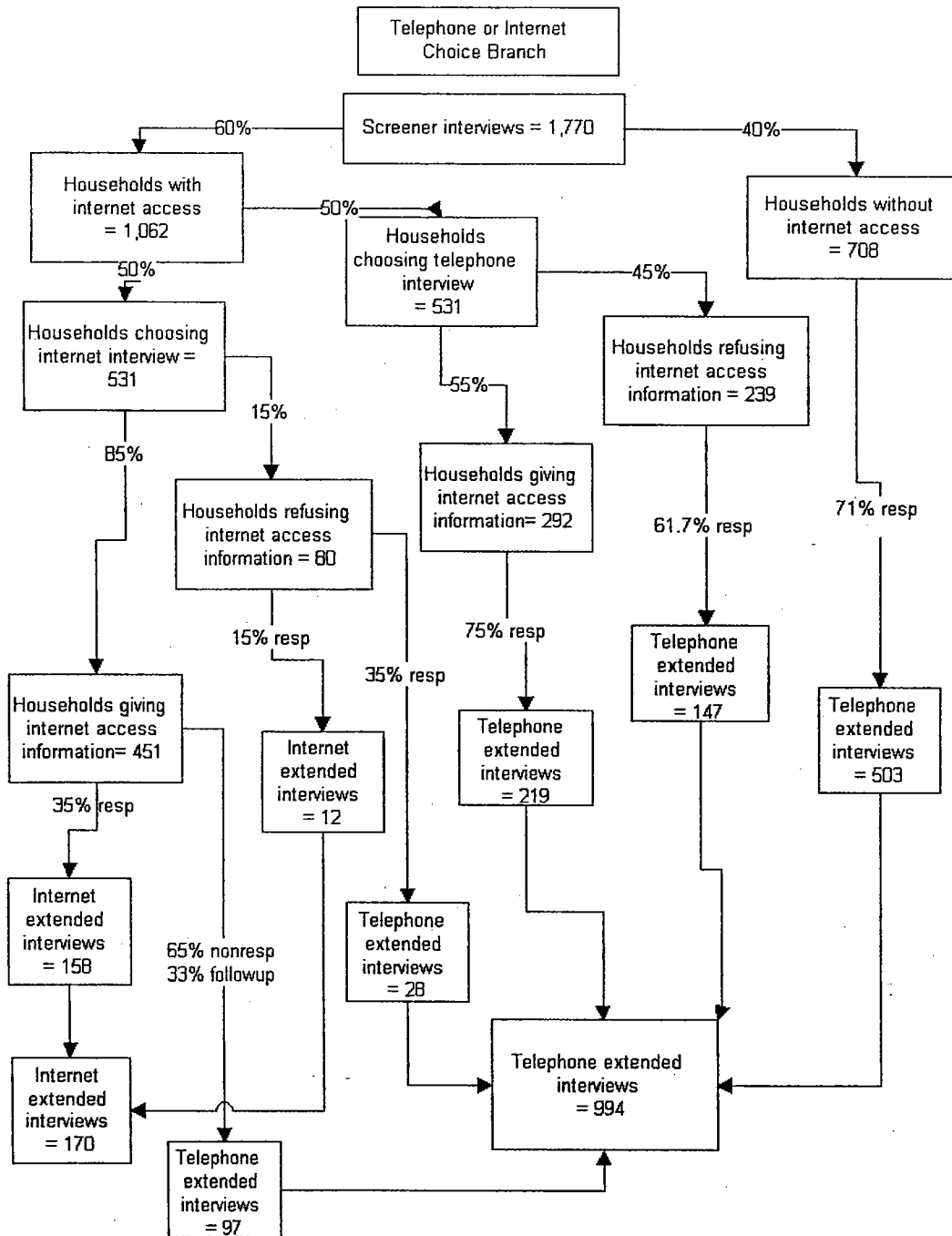


Figure A-3. Telephone or Internet choice branch