

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

FAX: 301-435-3710
To: Breen, Nancy
NCI
EPN/4005

Exempt #: 4470

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The California Health Interview Survey (CHIS) is a biennial population-based statewide local health survey (N 40-50,000 adults + adolescents + children). CHIS is administered by telephone in five languages to participants across the state of California. It is the only survey of its kind to provide statewide local estimates and estimates for small racial-ethnic groups with inadequate samples nationally. since 2001, the NCI had funded cancer control questions on CHIS that cover cancer risk factors and cancer screening behaviors

Original Request Received in OHSR on: 12/18/2008

Responsible NIH Research Investigator(s): Nancy Breen, PhD NCI

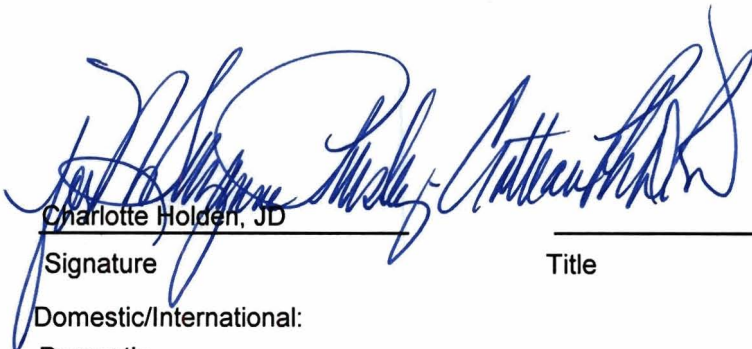
OHSR review of your request dated Mon, Dec 15, 2008 has determined that:

- 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.
- Confidentiality Agreement
- Reliance
- Amendment
- Other

Office Person SPC

Admin Assist. CB

Note:


Charlotte Holden, JD
Signature _____
Title _____
Date _____

12/22/2008

Date

Domestic/International:

Domestic

Human Subjects Data: Yes

Biologic Material: No

OHSR Use Only

1 2 3 4 5 6

#4470

**REQUEST FOR REVIEW OF RESEARCH ACTIVITY INVOLVING HUMAN
SUBJECTS**

INSTRUCTIONS: Please type directly on this form. You can expand the document if you need more space. If your research involves a survey or questionnaire, please attach it to this completed form.

Completed forms (with all required signatures) may be sent to OHSR by FAX (301-402-3443) or by mail (2C146). If you have any questions, call OHSR at (301) 402-3444.

Date: December 15, 2008

To: OFFICE OF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146

From: Nancy Breen
(Signature)

Through: Walter D...
(Signature of appropriate Official for IC, e.g., Lab/Branch Chief)

Name of NIH Principal Investigator(s): Dr. Nancy Breen

IC: NCI

Laboratory/Branch: Health Services and Economics Branch, Applied Research Program, Division of Cancer Control and Population Sciences

Building & Room: EPN 4094

Tel. No: 301.496.4675

FAX No: 301.435.3710

Is the Principal investigator an NIH employee? Yes No

If no, please explain: _____

1. What is the proposed research activity that you intend to perform at NIH (please use lay terms):

The California Health Interview Survey (CHIS) is a biennial population-based statewide local health survey (N~40-50,000 adults + adolescents + children). CHIS is administered by telephone in five languages to participants across the state of California. It is the only survey of its kind to provide statewide local estimates and estimates for small racial-ethnic groups with inadequate samples nationally. Since 2001, the NCI has funded cancer control questions on CHIS that cover cancer risk factors and cancer screening behaviors. These data enable researchers to better estimate health-related behaviors, use of health services, and cancer risk factors in small population groups.

The proposed research activity is to field cancer control content on the CHIS 2009 questionnaire. NCI plans to field items covering the following topics: colorectal, prostate, and breast cancer screening; cancer risk factors including walking, cigarette use, sun exposure, dietary intake, and medication use; and family history of cancer.

2. If applicable, list your non-NIH Collaborating Investigator(s).

Name	Institution	Address	Tel. #	FAX #
E. Richard Brown	UCLA Center for Health Policy Research	10960 Wilshire Blvd, Suite 1550		
	Los Angeles, CA 90024			
<hr/>				
<hr/>				
<hr/>				

3. Proposed start date of your research March 15, 2009
Proposed completion date March 14, 2012

4. Will you be _____ these samples or data?

Collecting Yes/No
Receiving Yes/No
Sending Yes/No

5. Do the samples or data:

(a) Already exist? Yes No

(b) Or are they being collected for the express purpose of this study? Yes No
If "yes," please describe: CHIS data are collected every 2 years on a random sample of California residents.

(c) Or a combination of (a) and (b)? Yes No

6. What role will you have in this research project? (Check all that apply)

Analyze samples/data only.

Consultant/advisor to collaborator(s) listed above.

Author of the protocol that is being implemented by your collaborating investigator (identified in question #2).

Co-authorship on publication(s)/manuscript(s) pertaining to this research.

___ You or NIH hold an IND for this research.

___ Decisional authority over the design or implementation of the research at the IRB approved site? If so, please explain.

___ Other (If necessary, use this space to describe your role in this research).

7. Where are the subjects of this research activity located?

CHIS is a biennial telephone survey, with subject located throughout the state of California. CHIS is designed to be representative of the California population and to provide local-level estimates, and therefore samples subjects in most counties throughout the state.

8. If human subjects are located elsewhere (not at NIH), will you have direct contact or intervention with them? (Examples: as subject's physician; in obtaining samples directly from the subject; by interviewing the subject?) ___ Yes No

9. What kind of human samples (e.g., tissue, blood) or data (e.g., private information, responses to questionnaires) will be involved in your research?

This research will involve questionnaire responses.

10. If the samples, data do not come from an IRB approved protocol, do they come from:

- (a) Repository ___ Yes No
- (b) Pathological waste ___ Yes No
- (c) Autopsy material ___ Yes No
- (d) Publicly available source ___ Yes No
- (e) Other _____

11. Please check the box(es) that apply(ies) to the samples/data that you will receive.

- (a) Samples and/or data will be anonymized/unlinked. (The samples/data cannot be linked to individual subjects by you or your collaborators at other sites.)
- (b) ___ Samples and/or data will be coded, however that code cannot be used by either the sender or the receiver to identify specific individuals.
- (c) ___ Samples and/or data will be coded so that the provider of the samples/data can link them to specific individuals but the receiver will not be able to do so.

12. Will you send results back to the provider(s) (listed in question 2 of this form)?

- (a) No, I will not send results back to the provider(s).
- (b) ___ Yes, I will send aggregate results to the provider(s).
- (c) ___ Yes, I will send results to the provider(s) that are linked to identifiable individuals.
If yes, does the provider intend to link your data to identifiable individuals?
___ Yes ___ No

13. Has the research activity that you are proposing in this form been approved by an Institutional Review Board (IRB) elsewhere?

Yes, the NIH research activity has been reviewed by the following IRB (s)
(Please provide the following information for **each** IRB):

University of California, Los Angeles

11000 Kinross Avenue, Suite 102
Box 951694
Los Angeles, California 90095-1694

E. Richard Brown, Ph.D.

California Health Interview Survey (2009)
UCLA IRB # G08-10-098-01

FWA00004642

No IRB review of the research activity described in question #1 above has taken place

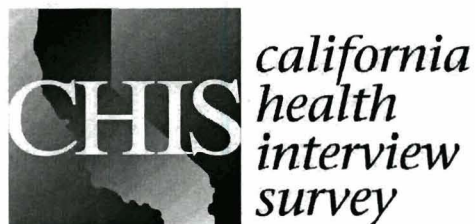
(** An FWA is a contract between the U.S. Department of Health and Human Services (DHHS) and an entity receiving DHHS funds to conduct clinical research that the latter will follow ethical guidelines and federal regulations for the protection of human subjects. For a list of domestic and international institutions go to <http://ohrp.cit.nih.gov/search/asearch.asp#ASUR>

14. Per NIH guidance***, have conflicts of interest by NIH employees, if any, been resolved?

Yes No

If your answer is no, please see your Clinical Director about this matter before proceeding with this research.

***The January 5, 2005 NIH Guide to Preventing Conflict of Interest applies to all research conducted at NIH, http://ohsr.od.nih.gov/New/mpafwa_docs.html



DRAFT: CALIFORNIA HEALTH INTERVIEW SURVEY 2009

NCI QUESTIONNAIRE ITEMS

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FOBT/SIGMOIDOSCOPY/COLONOSCOPY

PROGRAMMING NOTE QA09_A1
IF AAGE < 40 OR [AA2A = 1 (BETWEEN 18 AND 29) OR 2 (BETWEEN 30 AND 39)] OR
ENUM.AGE < 40 OR AGE IS UNKNOWN, GO TO NEXT SECTION;
ELSE CONTINUE WITH QA09_A1

QA09_A1 A stool or fecal blood test is done at home to check for colon cancer. You send your stool sample to the doctor's office or lab for testing. Have you ever done a stool or fecal blood test?

[INTERVIEWER NOTE: IF NEEDED, SAY: "Do not include over-the-counter test kits from a drugstore or pharmacy."]

- YES 1
- NO 2 [GO TO QA09_A4]
- REFUSED -7 [GO TO QA09_A4]
- DON'T KNOW -8 [GO TO QA09_A4]

QA09_A2 When did you do your most recent blood test using a home kit to check for colon cancer?

- A YEAR AGO OR LESS 1
- MORE THAN 1 YEAR AGO UP TO
2 YEARS AGO 2
- MORE THAN 2 YEARS AGO UP TO
5 YEARS AGO 3
- MORE THAN 5 YEARS AGO 4
- REFUSED -7
- DON'T KNOW -8

QA09_A3 What was the main reason you had your most recent stool blood test using a home kit? Was it...

- Part of a routine physical exam, 1
- Because of a problem, OR 2
- Some other reason? 3
- REFUSED -7
- DON'T KNOW -8

QA09_A4 A sigmoidoscopy and a colonoscopy are both tests that examine the bowel by inserting a tube in the rectum. The difference is that during a sigmoidoscopy, you are awake and can drive yourself home after the test; however, during a colonoscopy, you may feel sleepy and you need someone to drive you home. Have you ever had a colonoscopy?

- YES 1
- NO 2 [GO TO QA09_A7]
- REFUSED -7 [GO TO QA09_A7]
- DON'T KNOW -8 [GO TO QA09_A7]

QA09_A5 When did you have your most recent colonoscopy to check for colon cancer?

- A YEAR AGO OR LESS 1
- MORE THAN 1 UP TO 5 YEARS AGO 2
- MORE THAN 5 UP TO 10 YEARS AGO 3
- MORE THAN 10 YEARS AGO 4
- REFUSED -7
- DON'T KNOW -8

QA09_A6 What was the main reason you had your most recent colonoscopy? Was it...

- Part of a routine physical exam, 1
- Because of a problem, OR 2
- Some other reason? 3
- REFUSED -7
- DON'T KNOW -8

QA09_A7 Have you ever had a sigmoidoscopy?

- YES 1
- NO 2 [GO TO QA09_A11]
- REFUSED -7 [GO TO QA09_A11]
- DON'T KNOW -8 [GO TO QA09_A11]

QA09_A8 When did you have your most recent sigmoidoscopy to check for colon cancer?

- A YEAR AGO OR LESS 1
- MORE THAN 1 UP TO 5 YEARS AGO 2
- MORE THAN 5 UP TO 10 YEARS AGO 3
- MORE THAN 10 YEARS AGO 4
- REFUSED -7
- DON'T KNOW -8

QA09_A9 What was the main reason you had your most recent sigmoidoscopy? Was it...

- Part of a routine physical exam, 1
- Because of a problem, OR 2
- Some other reason? 3
- REFUSED -7
- DON'T KNOW -8

QA09_A11 In the past 5 years, has a doctor recommended that you have a sigmoidoscopy, colonoscopy, or stool blood test?

- YES 1
- NO 2
- DID NOT GO TO A DOCTOR
- IN PAST 5 YEARS 92
- REFUSED -7
- DON'T KNOW -8

PROGRAMMING NOTE QA09_A12:
 IF QA09_A4 = 2 (NEVER HAD COLONOSCOPY) AND QA09_A7 = 2 (NEVER HAD SIGMOIDOSCOPY), CONTINUE WITH QA09_A12 AND DISPLAY "never had";
 ELSE IF QA09_A5 = 4 (MOST RECENT COLONOSCOPY OVER 10 YEARS AGO) OR QA09_A8 = 6 (MOST RECENT SIGMOIDOSCOPY OVER 10 YEARS AGO), CONTINUE WITH QA09_D8 AND DISPLAY "not had" AND "in the last 10 years";
 ELSE GO TO NEXT SECTION

QA09_A12 What is the ONE most important reason why you have {never had/not had} one of these exams {in the last 10 years}?

- NO REASON/NEVER THOUGHT ABOUT IT..... 1
- DIDN'T KNOW I NEEDED
- THIS TYPE OF TEST 2
- DOCTOR DIDN'T TELL ME I NEEDED IT 3
- HAVEN'T HAD ANY PROBLEMS 4
- PUT IT OFF/LAZINESS 5
- TOO EXPENSIVE/NO INSURANCE/COST..... 6
- TOO PAINFUL, UNPLEASANT, OR EMBARRASSING 7
- HAD ANOTHER TYPE OF COLORECTAL EXAM 8
- DON'T HAVE A DOCTOR 9
- OTHER 91
- REFUSED -7
- DON'T KNOW -8

PROSTATE SPECIFIC ANTIGEN (PSA) TEST

PROGRAMMING NOTE QA09_A13:
 IF FEMALE GO TO QA09_A22;
 IF MALE AND (AGE < 40 OR BETWEEN 18 AND 29 OR BETWEEN 30 AND 39 OR ENUM.AGE < 45 OR IF AGE IS UNKNOWN), GO TO NEXT SECTION;
 ELSE CONTINUE WITH QA09_A13

QA09_A13 Have you ever heard of a PSA or "prostate-specific antigen" test to detect prostate cancer?
 A PSA test is a blood test to detect prostate cancer.

- YES 1
- NO..... 2 [GO TO NEXT SECTION]
- REFUSED.....-7 [GO TO NEXT SECTION]
- DON'T KNOW-8 [GO TO NEXT SECTION]

QA09_A14 Have you ever had a PSA test?

[INTERVIEWER NOTE: IF NEEDED, SAY: "A PSA test is a blood test to detect prostate cancer. It is also called a prostate-specific antigen test."]

- YES 1
- NO..... 2 [GO TO QA09_A19]
- REFUSED.....-7 [GO TO QA09_A19]
- DON'T KNOW-8 [GO TO QA09_A19]

QA09_A15 When did you have your most recent PSA test?

- A YEAR AGO OR LESS 1
- MORE THAN 1 YEAR AGO UP TO
2 YEARS AGO..... 2
- MORE THAN 2 YEARS AGO UP TO
3 YEARS AGO..... 3
- MORE THAN 3 YEARS AGO UP TO
5 YEARS AGO..... 4
- MORE THAN 5 YEARS AGO 5
- REFUSED.....-7
- DON'T KNOW-8

QA09_A16 What was the main reason you had this PSA test – was it part of a routine exam, because of a problem, or some other reason?

- Part of a routine physical exam,..... 1
- Because of a problem, OR 2
- Some other reason? 3
- REFUSED.....-7
- DON'T KNOW-8

QA09_A19 [{Before you had the PSA test}], did a doctor ever talk with you about the advantages and disadvantages of [{it}/the PSA test]?

- YES 1
- NO..... 2
- REFUSED-7
- DON'T KNOW-8

QA09_A20 [{Before you had the PSA test}], did a doctor ever tell you that some doctors recommend [{it}/the PSA test] and others do not?

- YES 1
- NO..... 2
- REFUSED-7
- DON'T KNOW-8

QA09_A21 Did a doctor or other health professional ever recommend that you have a PSA test?

- YES 1
- NO..... 2
- REFUSED-7
- DON'T KNOW-8

BREAST CANCER SCREENING

PROGRAMMING NOTE QA09_A28:
 IF 18 ≤ AAGE < 30, GO TO NEXT SECTION;
 IF MALE, SKIP TO NEXT SECTION;
 ELSE CONTINUE WITH QA09_A28 (INCLUDING WOMEN WITH AGE UNKNOWN)

QA09_A28 In the past 12 months, has a doctor examined your breasts for lumps?

[INTERVIEWER NOTE: IF NEEDED, SAY: "This is when a doctor touches your breasts to check for bumps, cysts, or abnormal growth."]

- YES 1
- NO 2
- REFUSED -7
- DON'T KNOW -8

QA09_A29 Have you ever had a mammogram?

[INTERVIEWER NOTE: IF NEEDED, SAY: "A mammogram is an x-ray taken of each breast separately by a machine that flattens or squeezes each breast." IF DEFINITION WAS NOT READ AND RESPONDENT ANSWERS "NO", READ DEFINITION BEFORE CODING]

- YES 1
- NO 2 [GO TO QA09_A41]
- REFUSED -7 [GO TO NEXT SECT]
- DON'T KNOW -8 [GO TO NEXT SECT]

QA09_A30 How many mammograms have you had in the last 6 years? Your best estimate is fine.

- _____ MAMMOGRAMS
- NONE 0 [GO TO QA09_A41]
- REFUSED -7
- DON'T KNOW -8

QA09_A31 How long ago did you have your most recent mammogram?

- A YEAR AGO OR LESS 1
- MORE THAN 1 UP TO 2 YEARS AGO 2
- MORE THAN 2 UP TO 3 YEARS AGO 3
- MORE THAN 3 UP TO 5 YEARS AGO 4
- MORE THAN 5 YEARS AGO 5
- REFUSED 7 [GO TO NEXT SECT]
- DON'T KNOW -8 [GO TO NEXT SECT]

QA09_A32 Was your most recent mammogram recommended by a doctor?

- YES 1
- NO 2
- REFUSED -7
- DON'T KNOW -8

PROGRAMMING NOTE QA09_A33:
 IF QA00_A31 = (3, 4, 5), THEN SKIP TO QA09_A34;
 ELSE CONTINUE WITH QA09_A33;

QA09_A33 Tell me the main reason you had a mammogram. Was it...

[INTERVIEWER NOTE: IF NEEDED, SAY: "The main reason is the most important reason."]

- Part of a routine exam, 1
- Because of a specific breast problem, 2
- A follow-up to a previously identified breast problem, 3
- Or due to family history? 4
- REFUSED 7
- DON'T KNOW -8

QA09_A34 Have you ever had a mammogram where the results were not normal?

- YES 1
- NO 2 [GO TO QA09_A41]
- REFUSED -7 [GO TO QA09_A41]
- DON'T KNOW -8 [GO TO QA09_A41]

QA09_A35 Have you ever had an operation to remove a lump from your breast?

- YES 1
- NO 2 [GO TO QA09_A39]
- DON'T KNOW -7 [GO TO QA09_A39]
- REFUSED -8 [GO TO QA09_A39]

QA09_A36 Did the lump turn out to be cancer?

- YES 1 [GO TO QA09_A38]
- NO 2
- REFUSED -7
- DON'T KNOW -8

QA09_A37 How many operations have you had to remove a lump that wasn't cancer?

- _____ NUMBER OF OPERATIONS [GO TO QA09_A39]
- REFUSED -7 [GO TO QA09_A39]

DON'T KNOW-8 [GO TO QA09_A39]

QA09_A38 Tell me how you first found out about your breast cancer. Was it by...

- Finding it yourself by accident..... 1
- Finding it yourself during a self breast examination..... 2
- Your husband or partner finding it..... 3
- Your doctor finding it during a routine breast exam..... 4
- Finding it by a mammogram..... 5
- Or some other way? (IF OTHER, SPECIFY):_____ 6
- DON'T KNOW-7
- REFUSED.....-8

QA09_A39 Did you have any other tests and/or surgery when your mammogram was not normal?

- YES 1
- NO..... 2 [GO TO QA09_A41]
- DON'T KNOW-7 [GO TO QA09_A41]
- REFUSED.....-8 [GO TO QA09_A41]

QA09_A40 What additional tests and/or surgery did you have?

[INTERVIEWER NOTE: CODE ALL THAT APPLY. IF NEEDED, SAY: "Any others?"]

- NO TESTS/NO SURGERY..... 1
- MASTECTOMY (SURGERY TO REMOVE BREAST)..... 2
- LUMPECTOMY (SURGERY TO REMOVE LUMP) 3
- NEEDLE BIOPSY 4
- ULTRASOUND TEST 5
- ANOTHER MAMMOGRAM 6
- CLINICAL BREAST EXAM..... 7
- REFUSED.....-7
- DON'T KNOW-8

PROGRAMMING NOTE QA09_A41:
 IF QA09_A29=2 OR QA09_A30 = 0 OR QA09_A31 > 2 years, CONTINUE WITH QA09_A41;
 ELSE GO TO PROGRAMMING NOTE QA09_A42;

QA09_A41 In the past 2 years, has a doctor recommended that you have a mammogram?

- YES 1
- NO..... 2
- REFUSED.....-7
- DON'T KNOW-8

PROGRAMMING NOTE QA09_A42:
 IF QA09_A41 = 1 (YES, DOCTOR RECOMMENDED A MAMMOGRAM) AND (QA09_A29=2 OR QA09_A30 = 0 OR QA09_A31 > 2 years), CONTINUE WITH QA09_A42;
 IF QA09_A31 = 3, 4, 5, -8 (MOST RECENT MAMMOGRAM > 2 YEARS or DK), DISPLAY "NOT had a mammogram in the past 2 years"; IF QA09_A29 = 2 (NEVER HAD MAMMOGRAM), DISPLAY "NEVER had a mammogram";
 ELSE GO TO NEXT SECTION;

QA09_A42 What is the ONE most important reason why you have {NEVER had a mammogram/NOT had a mammogram in the past 2 years}?

- NO REASON/NEVER THOUGHT ABOUT IT 1
- DIDN'T KNOW I NEEDED THIS TYPE OF TEST . 2
- DOCTOR DIDN'T TELL ME I NEEDED IT 3
- HAVEN'T HAD ANY PROBLEMS..... 4
- PUT IT OFF/LAZINESS 5
- TOO EXPENSIVE/NO INSURANCE/COST 6
- TOO PAINFUL, UNPLEASANT,
EMBARRASSING..... 7
- TOO YOUNG 8
- DON'T HAVE A DOCTOR..... 9
- OTHER..... 91
- REFUSED -7
- DON'T KNOW -8

WALKING FOR TRANSPORTATION AND LEISURE

QA09_F7 The next questions are about walking for transportation. I will ask you separately about walking for relaxation or exercise.

During the past 7 days, did you walk to get some place that took you at least 10 minutes?

- YES 1
- NO 2 [GO TO QA09_F10]
- UNABLE TO WALK 3 [GO TO QA09_F10]
- REFUSED -7 [GO TO QA09_F10]
- DON'T KNOW -8 [GO TO QA09_F10]

QA09_F8 In the past 7 days, how many times did you do that? [IF NEEDED, SAY: "Walk for at least 10 minutes to get some place."]

_____ TIMES PER WEEK

- REFUSED -7 [GO TO QA09_F10]
- DON'T KNOW -8 [GO TO QA09_F10]

QA09_F9 {How long did that walk take? / On average, how long did those walks take}?

_____ MINUTES

- REFUSED -7
- DON'T KNOW -8

QA09_F10 Sometimes you may walk for fun, relaxation, exercise, or to walk the dog. During the past 7 days did you walk for at least 10 minutes for any of these reasons? {Please do not include walking for transportation.}

- YES 1
- NO 2 [GO TO NEXT SECT]
- REFUSED -7 [GO TO NEXT SECT]
- DON'T KNOW -8 [GO TO NEXT SECT]

QA09_F11 In the past 7 days, how many times did you do that? [IF NEEDED, SAY: "Walk for at least 10 minutes to get some place."]

_____ TIMES PER WEEK [IF 0, GO TO NEXT SECT]

- REFUSED -7 [GO TO NEXT SECT]
- DON'T KNOW -8 [GO TO NEXT SECT]

QA09_F12 {How long did that walk take? / On average, how long did those walks take}?

_____ MINUTES

REFUSED.....-7

DON'T KNOW.....-8

CIGARETTES

QA09_F13 Now, I am going to ask about various health behaviors.
 Altogether, have you smoked at least 100 or more cigarettes in your entire lifetime?

- YES..... 1
- NO..... 2 [GO TO NEXT SECT]
- REFUSED.....-7
- DON'T KNOW.....-8

QA09_F14 Do you now smoke cigarettes every day, some days, or not at all?

- EVERY DAY..... 1
- SOME DAYS..... 2 [GO TO QA09_F16]
- NOT AT ALL 3
- REFUSED.....-7 [GO TO NEXT SECT]
- DON'T KNOW.....-8 [GO TO NEXT SECT]

PROGRAMMING NOTE QA09_F13
 IF QA09_F14 = 1 DISPLAY "On the average" and "do" and "now";
 IF QA09_F14 = 3 DISPLAY "Thinking back over the years you have smoked regularly, about" and "did" and "usually";

QA09_F15 (On the average/Thinking back over the years you have smoked regularly, about) how many cigarettes (do/did) you (now/usually) smoke a day?

[INTERVIEWER NOTE: IF R SAYS, A "PACK", CODE AS 20 CIGARETTES]

- ____ NUMBER OF CIGARETTES [GO TO QA09_F17]
- REFUSED.....-7 [GO TO QA09_F17]
- DON'T KNOW-8 [GO TO QA09_F17]

PROGRAMMING NOTE QA09_F16
 IF QA09_F14 = 2 (SMOKE SOME DAYS), CONTINUE WITH QA09_F16;
 ELSE CONTINUE WITH QA09_F17;

QA09_F16 In the past 30 days, when you smoked, how many cigarettes did you smoke per day?

[INTERVIEWER NOTE: IF NEEDED SAY, "On the days you smoked." AND IF R SAYS, A "PACK", CODE THIS AS 20 CIGARETTES]

- ____ NUMBER OF CIGARETTES
- REFUSED.....-7
- DON'T KNOW-8

QA09_F17 About how many years [have you/did you] smoke[d] cigarettes regularly?

_____ NUMBER OF YEARS

REFUSED.....-7
DON'T KNOW-8

SUN EXPOSURE/SUNSCREEN USE

PROGRAMMING NOTE QA09_F24
IF AGE ≥ 12, CONTINUE WITH QA09_F24;

QA09_F27 During the past 12 months, how many times have you had a sunburn?

[INTERVIEWER NOTE:IF NECESSARY SAY, "By 'sunburn' we mean even a small part of your skin turning red or hurting for 12 hours or more.]

_____NUMBER OF SUNBURNS

REFUSED.....-7

DON'T KNOW.....-8

QA09_F29 During the past 12 months, how many times have you used an indoor tanning device such as a sunlamp, sunbed, or tanning booth? Do NOT include a spray-on tan.

_____NUMBER OF TIMES

REFUSED.....-7

DON'T KNOW.....-8

DIETARY INTAKE

QA09_F40 During the past month, how often did {you/SP} drink regular soda or pop that contains sugar? Do not include diet soda. (You can tell me per day, per week or per month).

[INTERVIEWER NOTE: IF NEEDED SAY, "Do not include canned or bottled juices or teas. Your best guess is fine."]

- _____TIMES
- PER DAY..... 1
 - PER WEEK..... 2
 - PER MONTH..... 3
 - REFUSED..... - 7
 - DON'T KNOW..... - 8

QA09_F42 (During the past month), how often did you drink coffee or tea with sugar or honey added? Include coffee and tea you sweetened yourself and presweetened tea and coffee drinks such as Arizona Iced Tea and Frappuccino. Do not include artificially sweetened or diet coffee or diet tea. (You can tell me per day, per week or per month.)

- _____TIMES
- PER DAY..... 1
 - PER WEEK..... 2
 - PER MONTH..... 3
 - REFUSED..... - 7
 - DON'T KNOW..... - 8

QA09_F37 (During the past month), how often did you drink sweetened fruit drinks, sports or energy drinks, such as Kool-aid, lemonade, Hi-C, cranberry drink, Gatorade, Red Bull, or vitamin water? Include fruit juices you made at home and added sugar to. Do not include diet drinks or artificially sweetened drinks. (You can tell me per day, per week or per month.)

[IF NEEDED, SAY: "Do not include yogurt drinks or mineral water."]

- _____TIMES
- PER DAY..... 1
 - PER WEEK..... 2
 - PER MONTH..... 3
 - REFUSED..... - 7
 - DON'T KNOW..... - 8

QA09_F38 (During the past month), how often did {you/SP} eat cookies, cake, pie or brownies? Do not include sugar-free kinds. (You can tell me per day, per week or per month.)

[IF NEEDED, SAY: "Include ANY sweet pastries." "Do not include sugar-free kinds.."]

- _____TIMES
- PER DAY..... 1
 - PER WEEK..... 2
 - PER MONTH..... 3
 - REFUSED..... - 7
 - DON'T KNOW..... - 8

QA09_F39 (During the past month), how often did {you/SP} eat ice cream or other frozen desserts? Do not include sugar-free kinds. (You can tell me per day, per week or per month.)

[IF NEEDED, SAY: "Do not include sugar-free kinds. Your best guess is fine."]
[IF STRONGLY NEEDED, SAY: "Other examples are frozen yogurt and popsicles."]

- _____TIMES
- PER DAY..... 1
 - PER WEEK..... 2
 - PER MONTH..... 3
 - REFUSED..... - 7
 - DON'T KNOW..... - 8

QA09_F41 Now think about the past week. In the past 7 days, how many times did you eat fast food? Include fast food meals eaten at work, at home, or at fast-food restaurants, carryout or drive through.

[INTERVIEWER NOTE: IF NEEDED SAY, "Such as food you get at McDonald's, KFC, Panda Express or Taco Bell."]

- _____# OF TIMES IN PAST 7 DAYS
- REFUSED.....-7
 - DON'T KNOW.....-8

BREAST CANCER RISK (MENARCHE & LIVE BIRTHS)

PROGRAMMING NOTE QA09_D1:
 IF MALE, GO NEXT SECTION; ELSE CONTINUE QA09_D1;

QA09_D1 These next questions are about women's health.

How old were you when your periods or menstrual cycles started?

[INTERVIEWER NOTE: IF NEVER STARTED MENSTRUAL CYCLE, ENTER 96]

____ AGE
 NEVER STARTED MENSTRUAL CYCLE..... 96
 REFUSED.....-7
 DON'T KNOW-8

PROGRAMMING NOTE QA09_D2:
 IF QA09_D1 = -8 (DON'T KNOW), CONTINUE WITH QA09_D2; ELSE GO TO QA09_D3;

QA09_D2 Were you younger than 12, about 12-13, or older than 13?

YOUNGER THAN 12 1
 ABOUT 12 to 13 2
 OLDER THAN 13 3
 REFUSED.....-7
 DON'T KNOW-8

QA09_D3 Do you still have periods or menstrual cycles?

YES 1 [GO TO QA09_D4]
 NO..... 2
 REFUSED.....-7 [GO TO QA09_D4]
 DON'T KNOW-8 [GO TO QA09_D4]

QA09_D4 When did you have your last period or menstrual cycle?

____ AGE
 ____ MONTHS
 ____ YEARS

 REFUSED.....-7
 DON'T KNOW-8

QA09_D5 Have you ever given birth to a live born infant?

[INTERVIEWER NOTE: IF NEEDED, SAY: "A live born infant is an infant born alive."]

YES 1
 NO..... 2 [GO TO NEXT SECT]
 REFUSED.....-7 [GO TO NEXT SECT]

DON'T KNOW-8

[GO TO NEXT SECT]

QA09_D6 How old were you when your first child was born?

_____ YEARS OLD 2

REFUSED-7

DON'T KNOW-8

QA09_D7 In what year was your first child born?

_____ YEAR

REFUSED-7

DON'T KNOW-8

HOROMONE THERAPY, BIRTH CONTROL

PROGRAMMING NOTE QA09_D2
 IF AGE>44 CONTINUE WITH QA09_D2;
 ELSE GO TO QA09_D3;

QA09_D10 INTRO Are you taking any of the following medications?

QA09_D10 Hormone replacement therapy?

- YES 1
- NO..... 2
- REFUSED.....-7
- DON'T KNOW-8

QA09_D11 Tamoxifen or Nolvadex?

- YES 1
- NO..... 2
- REFUSED.....-7
- DON'T KNOW-8

PROGRAMMING NOTE QA09_D12
 IF AGE>44 CONTINUE WITH QA09_D12;
 ELSE GO TO QA09_D13;

QA09_D12 Raloxifen or Evista?

- YES 1
- NO..... 2
- REFUSED.....-7
- DON'T KNOW-8

PROGRAMMING NOTE QA09_D13
 IF AGE<55 CONTINUE WITH QA09_D13;
 ELSE GO TO SECTION E;

QA09_D13 Birth control pills, the patch, or birth control shots?

- YES 1
- NO..... 2
- REFUSED.....-7
- DON'T KNOW-8

QA09_D14 Have you ever taken hormone replacement therapy or HRT for menopausal symptoms?

- YES..... 1
- NO..... 2 **[GO TO NEXT SECTION]**
- REFUSED.....-7 **[GO TO NEXT SECTION]**
- DON'T KNOW.....-8 **[GO TO NEXT SECTION]**

QA09_D15 About how long ago did you stop using Hormone Replacement Therapy – was it...

- Less than 2 years ago 1
- More than 2 years up to 5 years ago 2
- More than 5 years ago..... 3
- REFUSED.....-7
- DON'T KNOW.....-8

QA09_D16 Some women go on and off hormone replacement therapy. Altogether, how long have you taken HRT?

- A YEAR AGO OR LESS 1
- MORE THAN 1 UP TO 2 YEARS 2
- MORE THAN 2 UP TO 4 YEARS 3
- MORE THAN 4 UP TO 8 YEARS 4
- MORE THAN 8 YEARS AGO 5
- REFUSED.....-7
- DON'T KNOW.....-8

FAMILY HISTORY OF CANCER

QA09_G1 What about your family? By family we mean only your blood relatives. Did your biological father or mother, full brother or sisters, or biological sons or daughters ever have cancer of any kind?

[IF NEEDED, SAY: "Do not include family members related through marriage such as a stepfather or stepsister, or family members who were adopted."]

- YES 1
- NO..... 2
- REFUSED.....-7
- DON'T KNOW.....-8

QA09_G2 What kind of cancer or cancers were these?

[CODE ALL THAT APPLY]
[PROBE: "Any others?"]

- BLADDER..... 1
- BLOOD 2
- BONE..... 3
- BRAIN 4
- BREAST 5
- CERVIX..... 6
- COLON..... 7
- ESOPHAGUS 8
- GALLBLADDER 9
- KIDNEY 10
- LARYNX-WINDPIPE..... 11
- LEUKEMIA..... 12
- LIVER..... 13
- LUNG 14
- LYMPHOMA 15
- MOUTH/TONGUE/LIP 16
- OVARY 17
- PANCREAS..... 18
- PROSTATE 19
- RECTUM..... 20
- SKIN 21
- SOFT TISSUE (MUSCLE OR FAT)..... 24
- STOMACH 25
- TESTIS 26
- THROAT-PHARYNX..... 27
- THYROID..... 28
- UTERUS 29
- OTHER 91
- REFUSED.....-7
- DON'T KNOW-8

PROGRAMMING NOTE QA09_G3

IF QA09_G2 = 21, THEN CONTINUE WITH QA09_G3;
ELSE SKIP TO PN QA09_G4;

QA09_G3 Was the skin cancer you mentioned non-melanoma, melanoma, or an unknown type?

[CODE ALL THAT APPLY]

- Non-melanoma..... 1
- Melanoma 2
- Unknown type 3
- REFUSED.....-7
- DON'T KNOW.....-8

PROGRAMMING NOTE QA09_G4

IF QA09_G2 = 5, THEN CONTINUE WITH QA09_G4;
ELSE SKIP TO PN QA09_G7;

QA09_G4 Was your mother ever diagnosed with breast cancer?

- YES 1
- NO..... 2
- REFUSED.....-7
- DON'T KNOW.....-8

QA09_G5 Do you have any sisters who have ever been diagnosed with breast cancer?

- YES 1
- NO..... 2 [GO TO PN QA09_G7]
- REFUSED.....-7 [GO TO PN QA09_G7]
- DON'T KNOW.....-8 [GO TO PN QA09_G7]

QA09_G6 How many?

_____ NUMBER OF SISTERS WITH BREAST CANCER

- REFUSED.....-7
- DON'T KNOW.....-8

PROGRAMMING NOTE QA09_G7

IF QA09_G2 = (7 OR 20), THEN CONTINUE WITH QA09_G7;
ELSE SKIP TO NEXT SECTION;

QA09_G7 Who was diagnosed with colon or rectal cancer?

[IF NEEDED, SAY: "Do NOT include STEP or HALF brothers and sisters."]

[CODE ALL THAT APPLY]

- MOTHER..... 1
- FATHER..... 2
- FULL BROTHER..... 3
- FULL SISTER..... 4
- BIOLOGICAL SON..... 5
- BIOLOGICAL DAUGHTER..... 6
- REFUSED.....-7
- DON'T KNOW.....-8

PROGRAMMING NOTE QA09_G8

IF QA09_G7 = (3, 4, 5, or 6), THEN CONTINUE WITH QA09_G8;
ELSE SKIP TO NEXT SECTION;

QA09_G8 How many?

_____ NUMBER OF FAMILY MEMBERS WITH COLON OR RECTAL CANCER

- REFUSED.....-7
- DON'T KNOW.....-8



APPROVAL NOTICE

OFFICE FOR PROTECTION OF RESEARCH SUBJECTS
11000 Kinross Avenue, Suite 102
169407
www.oprs.ucla.edu

DATE: November 24, 2008

TO: E. Richard Brown, Ph.D.
Principal Investigator

FROM: Alison A. Moore, M.D., M.P.H.
Chair, South General Institutional Review Board

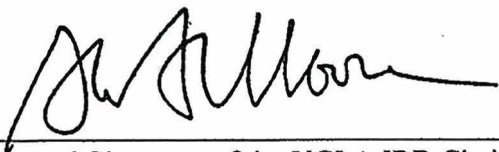
RE: UCLA IRB #G08-10-098-01
Approved by Full Committee Review
(Approval Period from 11/24/2008 through 11/17/2009)
California Health Interview Survey (2009)

Please be notified that the UCLA Institutional Review Board (UCLA IRB) has approved the above referenced research project involving human subjects in research. The UCLA's Federalwide Assurance (FWA) with the Department of Health and Human Services, Office for Human Research Protections is FWA00004642.

PLEASE COMPLY WITH THE FOLLOWING CODICIL(S) IMPOSED BY THE IRB:

- 1. This Approval Notice is issued for administrative purposes only. No subjects may be contacted, recruited, or enrolled in the 2009 California Health Interview Survey. All related IRB-approved forms will be held on file until the AMENDED Certificate of Confidentiality for this study is received and acknowledged (through issuance of a revised approval notice) by the UCLA IRB.**
- 2. Upon the expected enrollment of non-English speaking subjects or those who are not fluent in English, non-English recruitment materials and consent materials/scripts must be received and acknowledged by the UCLA IRB (through issuance of a revised approval notice) prior to implementation.**
- 3. No subjects may be contacted, recruited or enrolled in this study until copies of the Westat IRB approval (CHIS 2009 data collection contractor) and the State of California Committee for the Protection of Human Subjects are received and acknowledged by the UCLA SGIRB.**

APPROVAL NOTICE
IRB #G08-10-098-01



Approval Signature of the UCLA IRB Chair

PRINCIPLES TO BE FOLLOWED BY PRINCIPAL INVESTIGATORS:

As the Principal Investigator, you have ultimate responsibility for the conduct of the study, the ethical performance of the project, the protection of the rights and welfare of human subjects, and strict adherence to any stipulations imposed by the UCLA IRB. You must abide by the following principles when conducting your research:

1. Perform the project by qualified personnel according to the approved protocol.
2. Do not implement changes in the approved protocol or consent form without prior UCLA IRB approval (except in a life-threatening emergency, if necessary to safeguard the well-being of human subjects.)
3. If written consent is required, obtain the legally effective written informed consent from human subjects or their legally responsible representative using only the currently approved UCLA-IRB stamped consent form.
4. Promptly report all undesirable and unintended, although not necessarily unexpected adverse reactions or events, that are the result of therapy or other intervention, within ten working days of occurrence. All fatal or life-threatening events must be reported to the UCLA IRB in writing within 2 working days after discovery.
5. In clinical medical research, any physician(s) caring for your research subjects must be fully aware of the protocol in which the subject is participating.
6. No subjects may be identified, contacted, recruited, or enrolled until the contract with the sponsor is finalized by the University.
7. Ensure that all individuals who will interact with subjects and/or have access to identifiable research data have completed the UCLA Protection of Human Research Subjects Certification.
8. Ensure that all individuals who will access subjects' medical records have completed the UCLA HIPAA Research Training Certification.
9. If non-UCLA sites or personnel are involved, follow all study-specific requirements and consent processes approved by the UCLA IRB.

FUNDING SOURCE(S):

According to the information provided in your application, the funding source(s) for this research project may include the following: extramural.

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Thursday, December 18, 2008 12:19 PM
To: Breen, Nancy (NIH/NCI) [E]
Subject: Request for Review Rec'd-OHSR

Good afternoon Dr. Breen,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4470. Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

OHSR:
Ph: 301.402.3444
Fax: 301.402.3443

Thank you.

Sincerely,

Chris Brentin

Administrative Assistant

OD/OHSR/NIH

10 Center Drive, Rm. 2C-146

Bethesda, MD 20892

301-402-8631 (Direct)

301-402-3443 (Fax)

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, December 22, 2008 11:35 AM
To: Breen, Nancy (NIH/NCI) [E]
Subject: Request for Review Determination
Attachments: BreenN_NCI_DoesNotApply_4470_CY2008.pdf

Good morning Dr. Breen,

Attached, please find OHSR's determination of your Request for Review of Research, OHSR #4470.

Please feel free to contact OHSR with any questions.

Sincerely,

Chris Brentin

Administrative Assistant

OD/OHSR/NIH

10 Center Drive, Rm. 2C-146

Bethesda, MD 20892

301-402-8631 (Direct)

301-402-3443 (Fax)