

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

FAX: Exempt #: 4695

To: Bright, Mary Anne
NCI
Building 6116 - 6116 Executive Boulevard, 3049

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:

The NCI currently collects: 1. Customer service and demographic information from clients who contact NCI's Cancer Information Service (CIS) in order to properly plan, implement, and evaluate cancer education efforts, including assessing the extent by which the CIS impacts under served populations; 2. Smoking/tobacco use behavior of individuals seeking NCI's smoking cessation assistance in order to provide smoking cessation services tailored to the individual client's needs and track their smoking behavior at follow up

Original Request Received in OHSR on: 5/18/2009

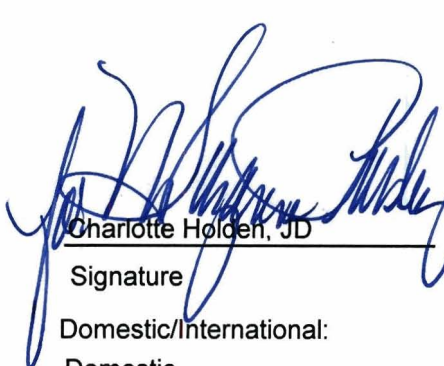
Responsible NIH Research Investigator(s): Mary Anne Bright, NCI


OHSR review of your request dated Fri, May 15, 2009 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


Acting Director, OHSR
Title

5/27/2009
Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
 1 2 3 4 5 6

4695

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: May 15, 2009

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

From: Mary Anne Bright
(Signature)

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

Name of NIH Principal Investigator(s): Mary Anne Bright

IC NCI Laboratory/Branch Office of Public Information and Resource Management, Office of Communications and Education

Building & Room No. 6116/3049 Tel. No. 302-594-9048 FAX No. 301-402-0555

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 NCI currently collects: 1. Customer service and demographic information from clients who contact NCI's Cancer Information Service (CIS) in order to properly plan, implement, and evaluate cancer education efforts, including assessing the extent by which the CIS impacts underserved populations; 2. Smoking/tobacco use behavior of individuals seeking NCI's smoking cessation assistance in order to provide smoking cessation services tailored to the individual client's needs and track their smoking behavior at follow up.

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

Name	Institution	Address	Tel. #	FAX #
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____
_____	_____	_____	_____	_____

3. Proposed start date of your research September 30, 2009
Proposed completion date September 30, 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? X Yes No

(b) Or are they being collected for the express purpose of this study? X Yes
 No

If "yes," please describe: _____

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

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

X 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). I direct the CIS program and use this information to plan, implement, and evaluate cancer education efforts that reach the public.

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

Subjects are located throughout the United States.

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?

Responses to customer service and demographic questions.

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 Individuals who respond to demographic and customer service questions _____

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):

_____	Name of institution that provided the review
_____	Address of reviewing institution
_____	Name of PI for the IRB approved protocol
_____	Title of IRB approved protocol and protocol #
_____	Federal Wide Assurance (FWA) number**

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



National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

DATE: May 1, 2009

TO: Mary Anne Bright, Associate Director
Office of Communications and Education, OPIRM, NCI

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: Cancer Information Service (CIS)

I have reviewed the NCI submission to OMB requesting approval for the revision to "NCI Cancer Information Service (CIS) on Demographic and Smoking/Tobacco Use" (OMB No. 0925-0208) and have determined that the Privacy Act will apply to this data collection.

Although the proposed methodologies will require the collection of personal information, data will not be retrieved by personal identifiers except when information is to be sent or clients have agreed to smoking cessation call backs. In these cases, personally identifiable information will be collected and retrieved by name, mailing address, e-mail address, and/or telephone number. Raw data from data collections that include personal information will not be retained once the data have been aggregated.

Three data collection efforts will be conducted: (1) a survey of a sample of CIS Telephone Clients; (2) a survey of a sample of Quitline Smoking Cessation Clients; and (3) a survey of a sample of LiveHelp Clients. The evaluation results will help CIS improve its program, products, and services.

The data collection is covered by NIH Privacy Act Systems of Record 09-25-0156, "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD".

If you have any questions, please contact my office at (301) 496-2832.

A handwritten signature in black ink, appearing to read "Karen M. Plá".

Karen M. Plá

Attachment

APPENDIX 2 A

**DATA COLLECTION INSTRUMENTS AND
ELECTRONIC CONTACT RECORD FORM (ECRF)**

**TELEPHONE QUESTIONS
(CUSTOMER SERVICE AND DEMOGRAPHICS QUESTIONS)**

File Help ROO Save ECRF Home Exit

*Service Number: A CANCER *Time Ranges:

No Service Provided:

*Purpose of Contact: Health concern (self)

*Type of User: 01 Patient diagnosed with cancer, no treatment Access: Telephone

Region: New York Case: Staff: Tester Region02 Date: 4/27/2009

ECRF

Service Demographics Contact Memo

Customer Service Previous Next Break off

COLLECT DEMOGRAPHICS ON THE CALL

Is caller distressed or terminally ill? Yes No

During our conversation, I already asked you some background information about yourself. I'd like to ask you just a few more questions that will help us to understand who we are serving. We appreciate your taking the time to answer these questions. Please know that all of your answers will be kept confidential. Is this OK?

Yes No Not able to ascertain

Public reporting burden for this collection...

Public reporting burden-- Webpage Dialog

Form approved: OMB No. 0925-0208, expires 09/30/2009

Public reporting burden for this collection of information is estimated to vary from 1 to 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. 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 (0925-0208).

OK

How did you find our number to call?

What is your home ZIP code?

Promotion?

Demographics

What is your age?

Are you female or male? Male

Which of these categories best describes you?
 Hispanic or Latino
 Black or African American

I am going to read another set of categories. Which of these categories best describes you?

What is the highest level of education you have completed? (read categories 1-6) College graduate

Is there a place you usually go to when you are sick or need advice about your health?

What kind of place do you go most often?

In the last 12 months, did you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?

Would you say you had this coverage during all 12 months or less than 12 months?

Which type of coverage did you have...

The final questions are about your family income. I understand that this is sensitive information and I would like to stress again that all of the information you provide is confidential.

What was your total household income from all sources before taxes last year? Just stop me when I get to the right category.

Including yourself, how many people living in your household are supported by this total household income? NUMBER OF PEOPLE

APPENDIX 2 D

**DATA COLLECTION INSTRUMENTS AND
ELECTRONIC CONTACT RECORD FORM (ECRF)**

PROACTIVE SMOKING CESSATION

“QUITLINE” QUESTION

SMOKING CESSATION (QUITLINE) PROACTIVE CALLBACK SERVICE CLIENTS

Burden statement:

Public reporting burden for this collection of information is estimated to average 1 minute per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** 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 (0925-0208). Do not return the completed form to this address.

Proactive smoking cessation callers are asked:

When was the last time you smoked a cigarette, even a puff?

APPENDIX 2 C

**DATA COLLECTION INSTRUMENTS AND
ELECTRONIC CONTACT RECORD FORM (ECRF)**

REACTIVE SMOKING CESSATION

“QUITLINE” QUESTIONS

SMOKING CESSATION "QUITLINE" REACTIVE DEMOGRAPHIC AND INTAKE QUESTIONS

OMB No. 0925-0208
Expiry Date: 9/30/2012

Example of burden statement in screen shot below:

Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** 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 (0925-0208). Do not return the completed form to this address.

ECRF Main - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Search Favorites Go Links

Address: https://dssecuretrain.nci.nih.gov/extranet/ecrf/cancer_main.asp

File Help ROO Save ECRF Home Exit

*Service Number: 4 CANCER *Time Ranges: []

No Service Provided: []

*Purpose of Contact: Health concern (self)

*Type of User: 01 Patient diagnosed with cancer, no treatment

Access: Telephone

Region: New York Case: Staff: Tester Region02 Date: 4/20/2009

ECRF

Service Demographics Contact Memo

Customer Service

Previous Next Break off

COLLECT DEMOGRAPHICS ON THE CALL

Is caller distressed or terminally ill? Yes No

During our conversation, I already asked you some background information about yourself. I'd like to ask you just a few more questions that will help us to understand who we are serving. We appreciate your taking the time to answer these questions. Please know that all of your answers will be kept confidential. Is this OK?

Yes No Not able to ascertain

Public reporting burden for this collection...

Have you used our service before? 2 No 2



How did you find our number to call? 304

NBC Nightly News 304

What is your home ZIP code? 20850

Promotion?

Current Smoking Cessation Intake Questions – Background Component

Address  https://cissecuretrain.nci.nih.gov/extranet/ecrf/SCIF_MDS.asp  Go Links >>

File Help ROO Save ECRF Home Exit

*Service Number: QUIT NOW *Time Ranges:

No Service Provided:

*Purpose of Contact:

*Type of User: 30 Cigarette smoker-help to Quit Access: Telephone

Region: New York Case: Staff: Tester Region02 Date: 3/23/2009

Smoking Cessation

Background Dependency Motivation Interventions Contact Service Demographics Memo

Background

Next Break off

Avg. Number of cigarettes smoked each day?

Age?

Sex?

Notes

Current Smoking Cessation Intake Questions – Dependency Component

Smoking Cessation



Background Dependency Motivation Interventions Contact Service Demographics Memo

Dependency

Previous

Next

Break off

Age when starting smoking cigarettes regularly?

First cigarette of the day after awakening?

Minutes

In life, number of quit attempts for 1 day or longer?

Duration (beyond a day) of successful quitting?

Days

In past year, number of quit attempts?

Longest time quit?

Days

Symptoms experienced after quitting?

- Feeling irritable, angry, agitated
- Mood swings, depressed, down, or blue
- Nervous, anxious, jumpy Cravings
- Trouble sleeping, nightmares, dreams
- Has not tried to quit before (1st quit attempt)
- Weight gain Increased appetite or hunger
- Tired, fatigued
- Feeling ill/sick/nausea/general malaise
- Headache Chest pain, shortness of breath
- Stress Unable to concentrate
- Dizzy/lightheaded Shakes
- Other

Triggers?

- Alcohol Sadness
- Anxiety Stress
- Fatigue After Meals
- Coffee Work breaks
- Driving Watching TV
- Phone calls Other

Used medication in the past?

- Yes
- Patches
 - Polacrilex Gums
 - Lozenges
- No
- Inhalers

Is medication to help quit a consideration this time?

- Yes
- Patches
 - Polacrilex Gums
 - Lozenges
- No
- Inhalers

Notes

[Previous](#) [Next](#) [Break off](#)

Current Smoking Cessation Intake Questions – Motivation Component

Smoking Cessation

Background Dependency Motivation Interventions Contact Service Demographics Memo

Motivation

Previous

Next

Break off

Most important reason for wanting to quit? Family or friends

Secondary Reason? To save money

Person most likely to positively influence effort to quit? Your spouse

Others in the household currently using tobacco products (one or more)? Yes No

- Your spouse
 - Your domestic partner/significant other
 - Your friend
 - Your parent
- Chewing Snuff Pipes
 Cigars Cigarettes

Notes

Current Smoking Cessation Intake Questions – Intervention Component

Smoking Cessation

Background Dependency Motivation **Interventions** Contact Service Demographics Memo

Intervention

Previous Next Break off

Interest in quitting within next 30 days? Yes

Confidence in ability to quit within the next 30 days? Not confident at all TIP

Quit Date? 03/25/2009 -- mm/dd/yyyy

Notes

Current Smoking Cessation Intake Questions – Callback Component

(May we contact you in the future to see how you're doing and offer additional assistance?)

Smoking Cessation - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites

Address https://cissecuretrain.nci.nih.gov/extranet/ecrf/SCIF_MDS.asp Go Links

File Help ROO Save ECRF Home Exit

*Service Number: QUIT NOW *Time Ranges: []

No Service Provided: []

*Purpose of Contact: []

*Type of User: 30 Cigarette smoker-help to Quit Access: Telephone

Region: New York Case: Staff: Tester Region02 Date: 3/23/2009

Smoking Cessation

Background Dependency Motivation Interventions **Contact** Service Demographics Memo

Contact

Previous Next Break off

Name (first/m/last) [] []

Organization: []

Address 1: []

Address 2: []

Address 3: []

City: []

County: []

State: []

ZIP Code [] - [] Find City by ZIP Code

E-mail: []

Phone: ([]) [] - [] Extension: [] Type: []
Home Note: []

Alt. Phone: ([]) [] - [] Extension: [] Type: []
Work Note: []

Previous Next Break off

Done Trusted sites

Current Smoking Cessation Intake Questions – Customer Service Component

Smoking Cessation - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Refresh Home Search Favorites

Address https://cissecuretrain.nd.nh.gov/extranet/ecrf/SCIF_MDS.asp Go Links

File Help
ROO Save ECRF Home Exit

' Service Number: QUIT NOW
' Time Ranges:

No Service Provided:

' Purpose of Contact:

' Type of User: 30 Cigarette smoker-help to Quit
Access: Telephone

Region: New York
Case: Staff: Tester Region02 Date: 3/23/2009

Smoking Cessation

Background Dependency Motivation Interventions Contact **Service** Demographics Memo

Service Information

Previous
Next
Break off

Intervention provided to client:

Subject of Interaction	Cancer Site/Type	Response	Resource Used	Special Codes	Actions
475					

Clear All
Select Wizard

Primary Language: English

Previous
Next
Break off

Done
Trusted sites

Current Smoking Cessation Intake and Follow-up Questions – Demographics Component

Demographics

What is your age?

Are you female or male? Female

Which of these categories best describes you? Not Hispanic or Latino

I am going to read another set of categories. Which of these categories best describes you?

American Indian or Alaska Native 100
 Asian 200
 Black or African American 300
 Native Hawaiian or Other Pacific Islander 400
 White 500

What is the highest level of education you have completed? (read categories 1-6) Some college

Is there a place you usually go to when you are sick or need advice about your health?

What kind of place do you go most often?

In the last 12 months, did you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?

Would you say you had this coverage during all 12 months or less than 12 months?

Which type of coverage did you have...

What was your total household income from all sources before taxes last year? Just stop me when I get to the right category.

Including yourself, how many people living in your household are supported by this total household income? NUMBER OF PEOPLE

Is there anything else...

APPENDIX 2 B

**DATA COLLECTION INSTRUMENTS AND
ELECTRONIC CONTACT RECORD FORM (ECRF)**

LIVEHELP QUESTIONS

LiveHelp Point of Access - Information Specialist Screen

File Help ROO Save ECRF Home Exit

No Service Provided: []

*Purpose of Contact: Health concern (self)

*Type of User: 01 Patient diagnosed with cancer, no treatment Access: LiveHelp

Region: New York Case: Staff: Tester Region02 Date: 4/27/2009

Electronic Contact Record Form

Service Contact Memo

Service Information (Provided Medical Disclaimer) Break off

COLLECT DEMOGRAPHICS ON THE CALL

Subject of Interaction	Cancer Site/Type	Response	Resource Used	Special Codes	Actions
325	08	042	10		4
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]
[]	[]	[]	[]	[]	[]

Clear All Select Wizard

Primary Language: English

During our conversation, I already asked you some background information about yourself. I'd like to ask you just a few more questions that will help us to understand who we are serving. We appreciate your taking the time to answer these questions. Please know that all of your answers will be kept confidential. Is this OK?

Informed consent? Yes No Not able to ascertain

Public reporting burden for this collection...



Form approved: OMB No. 0925-0208, expires 09/30/2009

Public reporting burden for this collection of information is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. **An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.** 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 (0925-0208).

OK

Have you used our service before?

2

No 2

Demographics URL:

Copy URL

<https://cisssecuredev.lmbps.com/demo/demographics.asp?USID=US11820>

Please Answer These Questions



Thank you for responding to our questions. For information about the confidentiality of your responses, click here. [Windows Internet Explorer](#)



Q: How can I be certain that the information I provide is confidential?

A: The Cancer Information Service is a confidential program. We will not obtain personal information about you unless you provide such information to us. If you identify yourself by sending an e-mail or ordering publications, we use this information to respond to your request and improve our customer service. Names and addresses of people ordering publications are kept in our publications fulfillment system for 3 months in order to follow up on orders, if necessary. They are then deleted from the system.

OK

To read more about this data collection, [click here.](#)

"Public reporting burden" -- Webpage Dialog

https://assecuredev.tmbps.com/demo/public_burden_livehelp.asp

Public reporting burden for this collection of information is estimated to average 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. 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 (0925-0208).

OK

https://assecuredev.tmbps.com/demo/public_burden_livehelp.asp

Internet

How did you find our site today?

Relative/friend

What is your age?

44

Are you female or male?

Female

Which of these categories best describes your ethnic background?

Not Hispanic or Latino

Which of these categories best describes your racial background?

(Select all that apply)

- American Indian or Alaska Native
- Asian
- Black or African American
- Native Hawaiian or Other Pacific Islander
- White

What is the highest level of education you have completed?

College graduate

What is your home ZIP code?

For use by U.S. residents only.

20850

Is there a place you usually go to when you are sick or need advice about your health?

YES

What kind of place do you go most often?

A doctor's office

In the last 12 months, did you have any kind of health care coverage, including health insurance, prepaid plans such as HMOs, or government plans such as Medicare?

YES

Would you say you had this coverage during all 12 months or less than 12 months?

All 12 months

Which type of coverage did you have...

Was it private, such as an HMO, Blue Cross, Kaiser, Aetna?

What was your total household income from all sources before taxes last year?

\$80,000 or more

Including yourself, how many people living in your household are supported by this total household income?

2

Clear Page Submit

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Monday, May 18, 2009 3:44 PM
To: Bright, Mary Anne (NIH/NCI) [E]
Subject: Request for Review Rec'd

Good afternoon Ms. Bright,

This email is to verify that OHSR has received your Request for Review of Research and it is currently being processed as OHSR #4695. 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

Program Support Assistant

OD/OHSR/NIH

10 Center Drive, Rm. 2C-146

Bethesda, MD 20892

301-402-8631 (Direct)

OHSR (NIH/DDIR)

From: Bright, Mary Anne (NIH/NCI) [E]
Sent: Wednesday, May 27, 2009 11:32 AM
To: OHSR (NIH/DDIR)
Subject: RE: BrightM_NCI_4695_CY2009

Good morning.

Yes, this is a service activity and is not research. Thank you for your review. Much appreciated.

Mary Anne

Mary Anne Bright
Associate Director, Office of Public Information and Resource Management
Office of Communications and Education
National Cancer Institute
phone - 301-594-9048
fax - 301-402-0555
brightma@mail.nih.gov

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From: OHSR (NIH/DDIR)
Sent: Wednesday, May 27, 2009 10:07 AM
To: Bright, Mary Anne (NIH/NCI) [E]
Subject: BrightM_NCI_4695_CY2009

Good Morning Ms. Bright:

Thank you for the opportunity to review your project to collect customer service and demographic information from clients who contact NCI's Cancer Information Service (CIS) and smoking cessation services tailored to the client's needs. OHSR has one point of clarification. Based on the information you have provided, it appears that this is a service activity; not a research activity. Please confirm this for OHSR records,

Best regards,

Suzanne Pursley-Crotteau, PhD, RN

Office of Human Subjects Research
Office of Intramural Research
National Institutes of Health
Bldg 10 Room 2C146
Bethesda, MD 20892

5/27/2009

Office Telephone: 301-402-3444
Office Fax: 301-402-3443