NCI/Office of Communications and Public Liaison

APPENDIX 6

OFFICE OF HUMAN SUBJECTS RESEARCH (OSHR) CLEARANCE

Exempt: #:

- Fro
- m: Office of Human Subjects Research (OHSR)

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

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; 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: 511 812009

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

OHSR review of vour request dated Fri, Mav 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.

- **Q** The activity is designated **EXEMPT.** and has been entered in the OHSR database. SE NOTIFY OHSR OF ANY SIGNIFICANT CHANGES THAT MAY AI TFR THF EMPT STATUS OF THIS RESFARCH ACTIVITY,
- **Q** NOT **EX-.** 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.
- **Q** Confidentiality Agreement
- **Q** Reliance

Amendment

Q Other

Office Person SPC Admin Assist. CB Note:

5/27/2009 Date

OHSR Use Only

Human Subjects Data: Yes

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 ØF HUMAN SUBJECTS RESEARCH, Building 10, Room 2C-146
From: Maly Cere negl
(Signature) Through:
(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? X 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 #
	art date of your research	
4. Will you be	these samples or	data?
Collecting Receiving Sending	Yes/No	
5. Do the sam (a) Already	ples or data: v exist?_X_YesNo	
No	hey being collected for the e	xpress purpose of this study? _ X_Yes
(c) Or a co	mbination of (a) and (b)?	X_YesNo
6. What ro	le will you have in this rese	arch project? (Check all that apply)
X Analyze	samples/data only.	
Consultant	/advisor to collaborator(s) lis	ted above.
Author of t	*	lemented by your collaborating investigator
Co-authors	hip on publication(s)/manuso	cript(s) pertaining to this research.
You or NII	H hold an IND for this resear	ch.

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

.

X____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?) _X_ 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 _x__ No

(b) Pathological waste Yes x No

(c) Autopsy material ____ Yes _x__ No

(d) Publicly available source _x _ 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) __X__ 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) <u>Samples and/or data will be coded so that the provider of the samples/data</u> 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) X____ 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?

13. Has the research activity <u>that you are proposing in this form</u> 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**

 X_N 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?

_X_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, <u>http://ohsr.od.nih.gov/New/mpafwa_docs.html</u>



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.

Muen m. Par

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 E	xit	
*Service Number:	4 Cancer 🔳	*Time Ranges:		<u>.</u>
No Service Provided:		7		
Purpose of Contact:			-	b
2012	01 Patient dragr	nosed with cancer, n	o treatment	Access: Telephone
Region: New York	Çase:	Staff: Tester Reg	3	Date: 4/27/2009
			ECRE	
service lacinations and s	Contact Memo			
Customer Service	2 Source Construction	n an a paratanga matain		
				Previous Next Break off
coule		APHICS ON TH	ECALL	
- Solata	Sheemser			
Is caller distressed or	15	C Yes C M		and the second
just a few more questio	os that will help u	is to understand whi	o we are ser	n about yourself. I'd like to ask you ving. We appreciate your taking the
time to answer these qu		know that all of you as これの これのt at		III be kept confidential. Is this OK?
	• Ye	95 · MO · MOL 30	NO (O ASCRITAT	20
Public report	ing burden for th	is collection	Call I	
Public reporting burde	en" Webpage Dial	Ù()		
Form approved OMB	And the following the state of	**************************************		
				from 1 to 7 minutes per response, gathering and maintaining the data
				ncy may not conduct or sponsor, and
a person is not requir	ed to respond to,	a collection of info	rmation unle	ss it displays a currently valid
OMB control number	Send comments	regarding this burden	estimate or a	ny other aspect of this collection of
Drive, MSC 7974, Bet	iggestions for redu hesda, MD 20892	-7974. ATTN PRA	(0925-0208)	Clearance Branch, 6705 Rockledge
		[
		<u>Cok</u>		
<u>1</u>				

.

How did you find our number to 300 1 call?		
What is your home ZIP code? 20850		
Promotion?		
Comographics		1
What is your age?	44	
Are you female or male?	2 - Male 2 -	
Which of these categories best describes you?	100 🗾 Hispanic or Latino 100 🖃	
Lam going to read another set of categories. Which of these categories bes describes you?	Black or African American 300	
What is the highest level of education you have completed? (read categories 1-6)	05 T College graduate 05 T	
Is there a place you usually go to when yo need advice about your health?	u are sick or YES 01	
What kind of place do you go most often?	A doctor's office 01	
In the last 12 months, did you have any kin care coverage, including health insurance, plans such as HMOs, or government plans Medicare?	orepaid YES 01 💽	
Would you say you had this coverage durir months or less than 12 months?	g all 12 All 12 months 01 👤	
Which type of coverage did you have		
	vate, such as an HMO, Blue Cross, Kaiser, Aetna? 02 🚬	
to stress again that all of the information y	come. I understand that this is sensitive information and I would like ou provide is confidential.	
What was your total household income fro before taxes last year? Just stop me wher right category.	n all sources I get to the \$80,000 or more 07 💌	
Including yourself, how many people living household are supported by this total hou- income?		
<pre>4</pre>	2 	<u>۲</u>
No promo found	Trusted sto	es 🕅 🛝 100% 🔻 🂋

APPENDIX 2 D

DATA COLLECTION INSTRUMENTS AND ELECTRONIC CONTACT RECORD FORM (ECRF)

> PROACTIVE SMOKING CESSATION "QUITLINE" QUESTION

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

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
Ele Edit Yew Favorites Tools Help
O Back - O - ⊠ C (µ) / Search ⊂ Favorites @ (µ + 🏭 🖃 ↓
Address 🗿 https://cissecuretrain.nci.nih.gov/extranet/ecrf/cancer_main.asp 🗾 🛃 Go 🛛 Links 🎽
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
Region: New York Case: Staff: Tester RegionD2 Date: 4/20/2009 ECRF
Service Demographics Contact Memo
Customer Service
COLLECT DEMOGRAPHICS ON THE CALL
Is caller distressed or terminally ill? C. Yes C 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 2 💌 No 2 💌
How did you find our number to call? 304 Image: Call of the second sec
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: Telephor	18
Region: Now York Case: Staff; Tester Region02 Date:	3/23/2009
Smoking Cessation	
Background Dependency Motivation Interventions Contact Service Demog	raphics Memo
–Background	
	Next Break off
Avg. Number of cigarettes smoked each day?	
Age?	
Sex?	
Notes	
	Å
	w l
	Lorent

.

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, agitat ✓ Mood swings, depressed, dov ✓ Nervous, anxious, jumpy ✓ C ✓ Trouble sleeping, nightmares, ✓ Has not tried to quit before (1 ✓ Weight gain ✓ Increased ap ✓ Tirred, fatigued ✓ Feeling ill/sick/nausea/genera ✓ Headache ✓ Chest pain, sho ✓ Stress ✓ Unable to concentr ✓ Dizzy/lightheaded ✓ Shakes ✓ Other 	vn, or blue Cravings dreams st quit attempt) petite or hunger Il malaise ortness of breath rate
Triggers?	「Anxiety 「Str 「Fatigue 「Aft 「Coffee 「Wo	er Meals
Used medication in the past?	♥Yes Patches Polacrilex Gums Lozenges C No Inhalers	,
Is medication to help quit a consideration this time?	<pre></pre>	
Notes		
	Previous N	Jext Break off

Current Smoking Cessation Intake Questions – Motivation Component

	Smaking Cessation	
Background Dependency Motivation Inte	rventions Contact Service Demographics Memo	
Motivation Most important reason for wanting to quit	Previous Next Break off	
Secondary Reason?	To save money	<u> </u>
Person most likely to positively influence effort to quit?	Your spouse	
Others in the household currently using tobacco products (one or more)?	Image: Second system Image: Second system Your spouse Image: Second system Your domestic partner/significant other Image: Second system Your friend Image: Second system Your parent Image: Second system	
Notes	A	
	<u>r</u> l	

Current Smoking Cessation Intake Questions – Intervention Component

	Smoking Cessation
ackground Dependency Motivation Interventio	ns Contact Service Demographics Memo
ntervention	Previous Next Break off
Interest in quitting within next 30 days?	Yas T
Confidence in ability to quit within the next 30 lays?	Not confident at all 💌 TIP
Quit Date?	03/25/2009 🔲 mm/dd/yyyy
lates	A
	<u>_</u>

Current Smoking Cessation Intake Questions – Callback Component

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

	👌 🖉 Search 🐘 Favorites 🚱 🕼 • 🖓 🚮 • 🖓 🏭	
dress 🗿 https://cissecuretr	ain.nci.nih.gov/extranet/ecrf/SCIF_MDS.asp	→ 🛃 Go Lin
le Help	ROO Save ECRF Home Exit	
Service Number:	QUIT NOW Y 'Time Ranges: Y	
No Service Provided:		
Purpose of Contact:		
+ Type of User: eqion: New York	30 Cigarette smoker-help to Quit Access: Telephone Case: Staff: Tester Region02 Date: 3/23/2009	
egioni ton	Smoking Cessation	
ackground Depender	ncy Motivation Interventions Contact Service Demographics Memo	
	in a second	
Contact		
ounder	Previous Next Break off	
Vame (first/m/last)		
Organization:		
- Address 1:		
Address 2:		
Address 3:		
City:		
County:		
State:		
	Find City by ZIP Code	
ZIP Code		
ZIP Code E-mail:		
ZTP Code E-mail:	() Extension: Type:	
	() - Extension: Type: Home T Note:	
E-mail: Phone:		
E-mail: Phone:	Home Y Note:	
E-mail:	Home Viote:	

Smoking Cessation - Microsoft Internet Explorer	
Edie Edit View Favorites Iools Help	
Back • ③ • 🖹 🗿 🕼 🖉 Search 🔅 Favorites 😨 🎧 • 🖓 📓 • 🗌 👯	- Go Links »
vgdress [2] https://cissecuretrain.ncl.nh.gov/extranet/ecrf/5CIF_MDS.asp	T Go Links »
ile 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 Gessation	
Background Dependency Motivation Interventions Contact Service Demographics Memo	
Service Information	
Previous Next Break off	
Intervention provided to client:	
Subject of Cancer Response Resource Used Special Codes Actions	
Interaction Site/Type	
Clear All Select Wizard	
Primary Language: English 🝸	
Previous Next Break off	
	🖞 🖉 Trusted sites
) Done	E IN HUSCOU SKES

Current Smoking Cessation Intake Questions – Customer Service Component

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

- Demographics	
What is your age?	55
Are you female or male?	1 V Female 1
Which of these categories best describes you?	200 💌 Not Hispanic or Latino 200 💌
I am going to read another set of categories. Which of these categories best describes you?	American Indian or Alaska Native 100 Asian 200 t 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)	04 - Some college 04 -
Is there a place you usually go to when you need advice about your health?	
What kind of place do you go most often?	A clinic, health center, or hospital clinic 02 💌
In the last 12 months, did you have any kind care coverage, including health insurance, p plans such as HMOs, or government plans si Medicare?	prepaid VCC 01
Would you say you had this coverage during months or less than 12 months?	ng all 12 All 12 months 01
Which type of coverage did you have	
	: both public and private? 03
What was your total household income from all sourc before taxes last year? Just stop me when I get to the right category.	the \$40,000 to \$59,000 05 🗾
Including yourself, how many people living in your household are supported by this total household income?	
Is there anything else	Previous Next Break off

APPENDIX 2 B

DATA COLLECTION INSTRUMENTS AND ELECTRONIC CONTACT RECORD FORM (ECRF)

LIVEHELP QUESTIONS

vericip i onic	01 Access 1110				
ile Help	ROO Save	ECRF Home	e Exit		
No Service Prov	ided:	2	อ		
Purpose of Con	tact: Health concer	n (self)	<u> </u>		
*Type of I	Jser: 01 Patient dia	gnosed with car	ncer, no treatment	<u>.</u>	Access: LiveHelp
tegion: New York	Case:		er Region02	Date: 4/27/200	9
		Electr	onic Contact Rec	ord Form	
Selections Contact	Memo		10		
Service Inform	ation (Provided Me	dical Disclaim	er)]
					Break off
	COLL	ECT DEMOGRA	PHICS ON THE CAL	l,	
Subject of Interaction	Cancer Site/Type	Response	Resource Used	Special Codes	Actions
325	08	042	10		4
[]			<u></u>		
		<u> </u>			
	ħ	<u> </u>			
, [
3		· · · · · · · · · · · · · · · · · · ·			
		1	1		
Clear All	Select Wizard	1			
Primary Language	э:	English	Ţ		
just a few more o	rsation, I already aske juestions that will help jese questions. Plea	h us to understa	nd who we are serv	ino. We apprecia	te your taking the 📋
			No C Not able to		
	Publ	ic reporting hurd	en for this collection	<u></u>	

LiveHelp Point of Access - Information Specialist Screen

....

🥭 "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 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).

X

	[OK			
Have you used our service before?	2 <u>•</u> No 2	<u>-</u>		
Demographics URL:			Copy URL	
https://cissecuredev.imbps.com/demo/	demographics.asp?USID=US1	.1820		

LiveHelp Point of Access - Client Screen

Pleas	e Answer These Questions		
Thank you for res	conding to our questions. For information about th	e confidentiality of your respon	ises,
<u>click here</u> . Window	s Internet Explorer		×
A	Q; How can I be certain that the information I provide is confiden	tial?	
	A: The Cancer Information Service is a confidential program. We us. If you identify yourself by sending an e-mail or ordering publi service. Names and addresses of people ordering publications ar orders, if necessary. They are then deleted from the system.	ications, we use this information to respond	to your request and improve our customer
	Ē	ок	
To read	I more about this data collection, click here.		
Public reporting b	urden" Webpage Diatog		
the time for reviewin completing and revie not required to res number. Send com including suggestion	den for this collection of information is estimated to ave g instructions, searching existing data sources, gathern ewing the collection of information. An agency may no spond to, a collection of information unless it displ ments regarding this burden estimate or any other aspe s for reducing this burden, to: NIH, Project Clearance D 20892-7974, ATTN: PRA (0925-0208).	g and maintaining the data needed, at conduct or sponsor, and a per ays a currently valid OMB con ct of this collection of information,	and rson is trol
	OK ps.com/demo/public_burden_live/help.asp		

.

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

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 HMC	D, 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

•

Glear Page Submit

-1

OHSR (NIH/DDIR)

From:OHSR (NIH/DDIR)Sent:Monday, May 18, 2009 3:44 PMTo: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 (NIHIDDIR)

From: Bright, Mary Anne (NIHINCI) [El Sent: Wednesday, May 27,2009 11 :32 AM To: OHSR (NIHIDDIR) 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 briahtma@mail.nih.aov

This e-mail message may contain privileged and confidential information intended for the use of the individual(s) or entity named above. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution, or copying of this message or its content is strictly prohibited. If you have received this message in error, please notify the sender immediately and delete or destroy the message without making a copy. Thank you.

From: OHSR (NIHIDDIR) Sent: Wednesday, May 27,2009 10:07 AM To: Bright, Mary Anne (NIHINCI) [EI Subject: BrightM-NU-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,

SW P-%y-&maku44, PCD;m

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

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