



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

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TO: Office of Management and Budget (OMB)

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SUBJECT: Nonmaterial/Non-substantive change request for:
NIH-AARP Comprehensive Lifestyle Interview by Computer (CLIC)
OMB #0925-0594

This is a request for OMB to approve a nonmaterial/non-substantive change to the NIH-AARP Comprehensive Lifestyle Interview by Computer (CLIC) Study. Based on correspondence with Margo Schwab at OMB on February 26, 2009, a nonmaterial/non-substantive change request is sufficient for the proposed addition. There is no change in the purpose or objectives of the study. Additionally, none of the changes being requested are substantive or contain new elements. Therefore, NCI is requesting these changes be considered under the Nonmaterial/Nonsubstantive Change Request procedure.

The *i*CLIC feasibility study utilizes recent developments in computer technology to build upon the success of the current NIH-AARP Diet and Health Study [OMB#s 0925-0423 and 0925-0587], which is a prospective cohort study of diet and cancer that began in 1995. Information gathered as part of the NIH-AARP *i*CLIC study, such as eligibility, response, and completion rates, as well as range of dietary intake, will be used for developing computerized questionnaire studies in larger cohorts.

As outlined in Supporting Statements A and B of the OMB package submitted for the NIH-AARP Comprehensive Lifestyle Interview by Computer (CLIC) feasibility study, four web-based instruments are being used to better assess dietary intake, physical activity, lifestyle and behavioral factors, and self-reported health conditions. The target population includes current AARP members aged 50 and older and members of the current cohort from 24 states known to have high-quality cancer registries. The NIH-AARP Comprehensive Lifestyle Interview by Computer (CLIC) feasibility study is utilizing recent developments in computer technology to build upon the success of the

current NIH-AARP Diet and Health Study [OMB#s 0925-0423 and 0925-0587], which is a prospective cohort study of diet and cancer that began in 1995.

1. Additional Mode of Contact

Currently, participants are being solicited to participate in the web-based NIH-AARP Comprehensive Lifestyle Interview by Computer (CLIC) feasibility study by paper mail invitation only. We propose inviting by email 10,000 current AARP members age 50 and over to participate in the feasibility study in order determine recruitment rates using this method of contact. In the actual group invited (of 15,000), very few AARP members have email addresses available, making this form of recruitment contact not viable. In order to determine the feasibility of enrollment into this web-based study by email invitation (allowing immediate links to the study website), we propose to randomly sample 10,000 AARP members with available email addresses, who have chosen the AARP membership option of providing their email addresses as a means of personal contact in addition to mailing addresses. Doing so will change the absolute universe from which we are recruiting and therefore, we have completed the time burden table for the potential additional participants recruited in the sample of 10,000. The following table documents the burden associated with the addition of persons who choose to enroll in the study from the additional recruitment of 10,000 AARP members.

Estimate of Annual Burden Hours

Type of Respondents	Instrument(s) Tested	Frequency of Response	Average Time per Response (Hours)	# of Respondents/ Pathway	Annual Hour Burden	
Senior Adults	Read Invitation	1	1/60	5000	83.333	
	Pre-Enrollment	1	10/60	688	114.667	
	Enrollment Process	1	5/60	680	56.667	
	Assigned Pathway 1					
	ACT-24	2	15/60	102	51.000	
	LHQ	1	20/60	102	34.000	
	DHQ	1	30/60	102	51.000	
	1 Web Re-entry	1	1/60	102	1.700	
	Assigned Pathway 2					
	ASA24	2	30/60	102	102.000	
	DHQ	1	30/60	102	51.000	
	LHQ	1	20/60	102	34.000	
	1 Web Re-Entry	1	1/60	102	1.700	
	Assigned Pathway 3					
	ACT-24	2	15/60	238	119.000	
	ASA24	2	30/60	238	238.000	
	LHQ	1	20/60	238	79.333	
	DHQ	1	30/60	238	119.000	
	1 Web Re-Entry*	1	1/60	238	3.967	
	Assigned Pathway 4					
	ACT-24	2	15/60	238	119.000	
	ASA24	2	30/60	238	238.000	
	LHQ	1	20/60	238	79.333	
	DHQ	1	30/60	238	119.000	
	3 Web Re-entries**	3	1/60	238	11.900	
	Evaluation Survey	1	1/60	680	11.333	
	Totals					1718.933

2. Study Name Change

A request is being made to change the name from the Comprehensive Lifestyle Interview by Computer (CLIC) Study to the *interactive* Comprehensive Lifestyle Interview by Computer (iCLIC) Study.