DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

TO: Office of Management and Budget

THROUGH: Seleda Perryman, DHHS Report Clearance Officer
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FROM: Kerry Grace Morrissey, MPH, Westat Project Director
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DATE: November 30, 2009

RE: NIH-AARP *interactive* Comprehensive Lifestyle Interview by Computer (iCLIC)
Nonmaterial / Nonsubstantive Change Request of OMB #0925 - 0594

This memo summarizes additional requested changes to the NIH-AARP *interactive* Comprehensive Lifestyle Interview by Computer (iCLIC) feasibility study. None of the changes being requested are substantive or contain new elements, and the results are not intended for publication. Therefore, NCI is requesting these changes be considered under the Nonmaterial/Nonsubstantive Change Request procedure.

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 dated May 6, 2008, 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 interactive Comprehensive Lifestyle Interview by Computer (iCLIC) feasibility study is utilizing 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], a prospective cohort study of diet and cancer that began in 1995.

Email as a Successful Mode of Contact

Recruitment of participants to the web-based NIH-AARP *interactive* Comprehensive Lifestyle Interview by Computer (iCLIC) feasibility study began in 2009 by paper mail invitation only. As more study participants in our cohort acquire and/or possess computer skills, it is important for the research team to assess the degree to which email contact is a successful mechanism for study recruitment. On April 9, 2009, our change

request to contact 10,000 AARP members age 50 and over by email to participate in a feasibility study to determine recruitment rates was approved.

We propose an addition of another 40,000 current AARP members to more accurately assess recruitment rates using this method of contact. The reason for increasing the overall numbers recruited via email invitation is that, thus far, the response rate to two hard copy invitations was less than 10%. Very few AARP members of the original sample of 15,000 had email addresses available, thus initially, email was not a promising contact mechanism. However, a greater number of incoming AARP members appear to have email addresses as indicated by their selection of the AARP membership option to provide email addresses as a means of personal contact, thus expanding the absolute universe from which we are recruiting. Moreover, it highlights the importance of validating email as a successful mechanism for study contact.

Use of an email invitation also permits greater flexibility in customizing reasonable, repeated email invitations to a potential participant and provides an interested respondent with easy, direct access to the study website by clicking on an imbedded link in the email invitation. We wish to test if these electronic functions will aid in boosting response rates. This increased sample size is also requested because it is not expected that all email invitations will reach the potential participant; email is sometimes filtered or placed in junk or spam boxes and not received by the intended recipient. When this happens, the overall sample size is reduced in effect because the intended recipient never has the opportunity to read the invitation, and therefore has no associated burden. Given that at this time we do not have an accurate assessment of the extent to which recipients will open and read the email invitation, we will calculate the opening of email invitations in order to determine actual contact with potential participants. Such information will provide a much better determination of initial sample size needed to achieve desired response rates in a large future study.

Additionally, an increased sample size will support the full evaluation of completion rates for the various instruments and will allow the assessment of the range of dietary intake, physical activity and lifestyle behaviors among those responding, information that cannot be assessed without adequate completion of the instruments.

In summary, this change request approval for distribution of an email invitation to an additional 40,000 randomly selected new AARP members interested in receiving email contact from AARP. In keeping with OMB requirements, the Time Burden Table documents the burden associated with the recruitment of the additional 40,000 persons who proceed to study enrollment and completion.

The estimates presented in the table (page 3) are based upon the following assumptions: only half of the 40,000 will read the invitation, resulting in 20,000 respondents, of these, 2,000 (10%) will proceed to pre-enrollment, with 1,920 (96%) completing the enrollment process. It is the same 1,920 respondents who complete the enrollment process, each questionnaire, and the evaluation survey.

Estimate of Additional Annual Burden Hours for iCLIC

Type of Respondents	Instrument(s) Tested	Frequency of Response	Average Time per Response (Hours)	# of Respondents	Annual Hour Burden
Senior Adults	**Read Invitation**	1	1/60	20,000	333.33
	Pre-Enrollment	1	10/60	2,000	333.33
	Enrollment Process	1	5/60	1,920	160.00
	Questionnaires				
	ASA24	2	30/60	1,920	1,920.00
	ACT-24	2	15/60	1,920	960.00
	LHQ	1	20/60	1,920	640.00
	DHQ	1	30/60	1,920	960.00
	3 Web Re-entries**	3	1/60	1,920	96.00
	Evaluation Survey	1	1/60	1,920	32.00
Totals					5,434.67