

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, Canada, and Brazil. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: Health Canada; the European Commission Directorate-General for Internal Market, Industry, Entrepreneurship, and Subject Matter Experts; the Ministry of Health, Labor, and Welfare of Japan; the Brazilian Health Surveillance Agency; and FDA. All decisions made by consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

Agenda: We will make the agenda for the public meeting available on the Internet at <http://www.fda.gov/Cosmetics/InternationalActivities/ICCR/default.htm>. Depending on the number of requests for oral presentations, we intend to have an agenda available by September 3, 2015. We may use the information that you provide to us during the public meeting to help us prepare for the November 4–6, 2015, ICCR–9 meeting.

Dated: July 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS–0990–0279–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990–0279, which expires on August 31, 2015. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before September 14, 2015.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990–0279 for reference.

Information Collection Request Title: Institutional Review Board Form—OMB No. 0990–0279, Assistant Secretary for Health, Office for Human Research Protections.

Abstract: Section 491(a) of Public Law 99–158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (e.g., a grant, contract, or cooperative agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to ensure protection of the rights and welfare of the human research subjects. IRBs are boards, committees, or groups formally designated by an entity to review,

approve, and have continuing oversight of research involving human subjects.

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990–0279, Institutional Review Board (IRB) Registration Form. This form was modified in 2009 to be consistent with IRB registration requirements, 45 CFR part 46, subpart E and 21 CFR 56.106 that were adopted in July 2009 OHRP and FDA, respectively.

Need and Proposed Use of the Information: The information collected through the Institutional Review Board registration collection requirements is the minimum necessary to satisfy the registration requirements of Section 491 (a) of the Public Health Service Act, 45 CFR part 46, subpart E and 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA’s regulations, IRBs in the United States that review clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and, IRBs in the United States that review clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

Burden Statement: The burden estimates for the IRB registration form include those approved by OMB in March 2015 under Control Number 0990–0263, the Assurance Identification/IRB Certification/Declaration of Exemption form (former Optional Form 310). Those burden estimates are not included as part of the burden estimate presented below.

ESTIMATED ANNUALIZED BURDEN TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration 0990–0279	5,900	2	1	11,800
	500	2	1	1,000
Total	12,800

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Terry S. Clark,
Asst Information Collection Clearance Officer.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 21, 2015 (80 FR 22211), and allowed 60-days for public comment. No public comments

were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202-395-6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Kelly Yu, Ph.D., Division of Cancer Prevention, 9609 Medical Center Drive, Room 5E230, Rockville, MD 20850 call non-toll-free number 240-276-7041 or Email your request, including your address to: *yuke@mail.nih.gov*. Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) 0925-0407, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for a revision of the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO). This trial was designed to determine if cancer screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which caused an estimated 253,320 deaths in the U.S in 2014. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since then. Recruitment was completed in 2001, baseline cancer screening was completed in 2006, and data collection continues on the current cohort of 77,281 participants who are actively being followed. The additional follow-up will provide data that will clarify further the long term effects of the screening on cancer incidence and mortality for the four targeted cancers. Further, demographic and risk factor information may be used to analyze the differential effectiveness of cancer screening in high versus low risk individuals.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 26,320.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average time per response (minutes/hour)	Annual burden hours
Annual Study Update (ASU) Form ...	Participants who complete the ASU	77,281	1	5/60	6,440
ASU Telephone Script	Non Responders to the ASU	3,091	1	5/60	258
Authorization to Release Medical Records.	Participants who report new cancers	2,700	1	3/60	135
Health Status Questionnaire (Female) (HSQ).	Female participants who complete the HSQ.	960	1	5/60	80
Health Status Questionnaire (Male) (HSQ).	Male participants who complete the HSQ.	1,040	1	5/60	87
Medication Use Questionnaire (MUQ).	Participants who complete the MUQ	77,281	1	15/60	19,320

Dated: June 23, 2015.
Karla Bailey,
NCI Project Clearance Liaison, National Institutes of Health.
 [FR Doc. 2015-17340 Filed 7-14-15; 8:45 am]
BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer

Institute Special Emphasis Panel, July 22, 2015, 11:00 a.m. to 04:00 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, 2W194, Rockville, MD, 20850 which was published in the **Federal Register** on June 23, 2015, 80 FR 35964.

The meeting notice is amended to change the date of the meeting from July