



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request: A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Nathaniel Rothman, Senior Investigator, Division of Cancer Epidemiology and Genetics, 9609 Medical Center

Drive MSC 9776 Room 6E134, Bethesda, Maryland 20892 or call non-toll-free number (240)-276-7169 or E-mail your request, including your address to: rothmann@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI), 0925-0654, Expiration Date 10/31/2015 –REVISION, National Institutes of Health (NIH).

Need and Use of Information Collection: Incidence rates of certain lymphomas have increased in the United States and in many other parts of the world. The contribution of environmental, occupational, and genetic factors to the cause of lymphoma and leukemia has generated a series of novel findings from epidemiological studies conducted in the United States that have attempted to explain this increase. However, none of the chemical associations have been conclusively established and the identification of the key, functional alleles in gene regions associated with risk of lymphoma requires further elucidation. Further, the ability to follow-up, confirm, and extend these observations in the United States is limited by the low prevalence and limited range of several important chemical and viral exposures and the high to complete linkage disequilibrium among key candidate genetic loci in Western populations. To optimize the ability to build on and clarify these findings, it is necessary to investigate populations that differ from those in the West in both exposure patterns and underlying genetic structure. A multidisciplinary case-control study of lymphoma in Asia, where lymphoma rates have also risen, provides an opportunity to replicate and extend recent and novel observations made in studies in the West in a population that is distinctly different with regard to patterns of key risk factors, including range of exposures, prevalence of exposures, correlations between exposures, and variation in gene regions of particular interest. It will also improve the ability to understand the causes of certain types of rare lymphoma tumors in the United States that occur at much higher rates in Asia. As such, AsiaLymph will confirm and extend previous findings and yield novel insights into the causes of lymphoma and leukemia in both Asia and in the United States. The major postulated risk factors for evaluation in this study are chemical exposures (i.e., organochlorines, trichloroethylene, and benzene) and genetic susceptibility.

Other factors potentially related to lymphoma, such as viral infections, ultraviolet radiation exposure, medical conditions, and other lifestyle factors will also be studied. Patients from 11 participating hospitals will be screened and enrolled. There will be a one-time computer-administered interview, and patients will also be asked to provide a one-time blood and buccal cell mouth wash sample and lymphoma cases will be asked to make available a portion of their pathology sample.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 3,086.

Estimated Annualized Burden Hours

Types of Respondents	Instrument	Number of Respondents	Frequency of Response	Time per Response (Hours)	Annual Burden Hours
Potential Study Subjects	Screening Questions	1,804	1	5/60	150
Consented Patient Cases	Core Questionnaire & Occupational Job Module	967	1	105/60	1,692
Consented Patient Controls	Core Questionnaire & Occupational Job Module	300	1	105/60	525
Study Pathologists	Pathology sample request and tracking form	10	97	5/60	81
Interviewers	Tracking forms	15	85	30/60	638

Dated: August 24, 2015

Karla Bailey

Project Clearance Liaison

National Cancer Institute, NIH

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