DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health, 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 August 28, 2015, page number 52325 and allowed 60-days for public comment. One public comment was 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: To obtain a copy of the data collection plans and instruments, 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, Rockville, MD 20850 or call non-toll-free number (240)-276-7169 or E-mail your request, including your address to: rothmann@mail.nih.gov.

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 cases with lymphoma or leukemia 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 3,262.

Estimated Annualized Burden Hours

Table A.12-1. Estimates of Annual Burden Hours					
Types of Respondents	**Instrument**	**Number of Respondents**	**Frequency of Response**	**Time per Response (Hours)**	**Annual Burden Hours**
Potential Study Subjects	Screening Questions	2,110	1	5/60	176
Eligible Potential Study Subjects	Consent Form	1,801	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: October 16, 2015.

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National Cancer Institute, NIH.

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