

including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to 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.

*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 Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA\_submission@omb.eop.gov* or by fax to 202-395-6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: George Chacko, Office of Planning, Analysis, and Evaluation, Center for Scientific Review, 6701 Rockledge Drive, Suite 3030, Bethesda, MD 20892 or call non-toll-free at 301-435-1111 or email your request, including your address to: *chackoge@mail.nih.gov*.

*Comments 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.

**George Chacko,**

*Director, Office of Planning, Analysis, and Evaluation, Center for Scientific Review, National Institutes of Health.*

[FR Doc. 2012-4271 Filed 2-23-12; 8:45 am]

**BILLING CODE 4104-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Proposed Collection; 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 (NCI), 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.

*Proposed Collection: Title:* A Multi-Center International Hospital-Based Case-Control Study of Lymphoma in Asia (AsiaLymph) (NCI). *Type of Information Collection Request:* Emergency. *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 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 NHL 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 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 19 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. *Frequency of Response:* Once. *Affected Public:* Individuals. *Type of Respondents:* Newly diagnosed patients with lymphoma or patients undergoing surgery or other treatment for non-cancer related medical issues who live in Taiwan and in Hong Kong, Chengdu and Tianjin, China will be enrolled at treating hospitals. The annual reporting burden is estimated at 5,302 hours (see Table below). There are \$77,000 in Capital Costs, Operating Costs, and/or Maintenance Costs to report.

**ESTIMATES OF ANNUAL BURDEN HOURS**

| Category of respondents | Types of respondents          | Number of respondents | Frequency of response | Average time per response (minutes/hour) | Annual burden hours |
|-------------------------|-------------------------------|-----------------------|-----------------------|--|---------------------|
| Individuals .....       | Patients to be Screened ..... | 3,100                 | 1                     | 5/60                                     | 258                 |
|                         | Patients with Lymphoma .....  | 1,100                 | 1                     | 105/60                                   | 1,925               |
|                         | Other Patients .....          | 1,100                 | 1                     | 105/60                                   | 1,925               |
|                         | Study Pathologists .....      | 19                    | 58                    | 5/60                                     | 92                  |
|                         | Interviewers .....            | 19                    | 116                   | 30/60                                    | 1,102               |
| <b>Total .....</b>      |                               |                       |                       |  | <b>5,302</b>        |

*Request for Comments:* Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance 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.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Nathaniel Rothman, Senior Investigator for the Occupational and Environmental Epidemiology Branch, Division of Epidemiology and Genetics, National Cancer Institute, 6120 Executive Boulevard, Room 8118, Rockville, MD 20892 or call non-toll-free number 301-496-9093 or email your request, including your address to: *rothmann@mail.nih.gov*.

*Comments 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.

Dated: February 21, 2012.

**Vivian Horovitch-Kelley,**

*NCI Project Clearance Liaison, National Institutes of Health.*

[FR Doc. 2012-4347 Filed 2-23-12; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of

federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

**ADDRESSES:** Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804; telephone: 301-496-7057; fax: 301-402-0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

#### **Polyclonal Antibodies Useful for the Detection of Vangl1 and Vangl2 Proteins Which Play a Role in Developmental Processes**

*Description of Technology:* Vangl1 (Van Gogh like 1) and Vangl2 (Van Gogh like 2) are two core proteins mediating establishment of Planar Cell Polarity (PCP), which refers to the polarity of epithelial cells within a plane orthogonal to their apical-basal axis. Disruption of core PCP proteins leads to many developmental defects, including open neural tube, misorientation of sensory hair cells in the inner ear, polycystic kidney disease and skeletal deformations. In humans, mutations in Vangl1 and Vangl2 have been identified in patients with neural tube defects, such as spina bifida, the most common permanently disabling birth defect in the United States. NHGRI researchers have recently generated rabbit polyclonal antibodies against Vangl1 and phosphorylated Vangl2 proteins that are suitable for endogenous Vangl1 and Vangl2 detection.

*Potential Commercial Applications:* Anti-Vangl1 and Vangl2 antibodies could be used in the development of diagnostic and therapeutic treatments for PCP-related developmental defects.

*Development Stage:*

- Pre-clinical.
- In vitro data available.

*Inventors:* Yingzi Yang and Bo Gao (NHGRI); Yingzi Yang and Hai Song (NHGRI).

*Publications:*

1. Gao B, et al. Wnt signaling gradients establish planar cell polarity by inducing Vangl2 phosphorylation through Ror2. *Dev Cell*. 2011 Feb 15;20(2):163-176. [PMID 21316585]
2. Song H, et al. Planar cell polarity breaks bilateral symmetry by controlling ciliary positioning. *Nature*. 2010 Jul 15;466(7304):378-382. [PMID 20562861]

*Intellectual Property:* HHS Reference Nos. E-135-2011/0 and E-136-2011/

0—Research Tools. Patent protection is not being pursued for these technologies.

*Licensing Contact:* Suryanarayana (Sury) Vepa, Ph.D., J.D.; 301-435-5020; *vepas@mail.nih.gov*.

#### **Novel Biomarkers for Alcohol-Induced Liver Disease (ALD)**

*Description of Technology:* Alcohol-induced liver disease (ALD) is a leading cause of non accident-related deaths worldwide. ALD is reversible if identified in the early stages, but early diagnosis is difficult with existing tools. One problem associated with developing a new diagnostic tool is the genetic background associated heterogeneity in physiological responses to chronic alcohol consumption. The inventors of the present technology have solved this problem and have discovered background-independent novel biomarkers for ALD. In the current studies, the inventors generated two genetically distinct lines of PPARalpha-null mice and evaluated the levels of urine metabolites after alcohol exposure. The inventors have identified indole-3-lactic acid and phenyllactic acid as putative biomarkers for ALD. Indole-3-lactic acid and phenyllactic acid levels were significantly elevated in both lines of PPARalpha-null mice after two to three months of alcohol administration. The inventors had identified indole-3-lactic acid and phenyllactic acid to be background independent markers for ALD.

*Potential Commercial Applications:* Useful for early non-invasive screening of ALD in large numbers of subjects irrespective of their genetic background.

*Competitive Advantages:*

- Easily adaptable for the development of highly sensitive spectroscopy-based assay kits.
- Amenable for the development of high-throughput mass spectrometric analysis of urine samples to detect early onset of ALD.

*Development Stage:*

- Early-stage.
- Pre-clinical.
- In vivo data available (animal).

*Inventors:* Soumen Kanti Manna and Frank J. Gonzalez (NCI).

*Publications:*

1. Manna SK, et al. UPLC-MS-based urine metabolomics reveals indole-3-lactic acid and phenyllactic acid as conserved biomarkers for alcohol-induced liver disease in the Ppara-null mouse model. *J Proteome Res*. 2011 Sep 2;10(9):4120-4133. [PMID 21749142]
2. Manna SK, et al. Identification of noninvasive biomarkers for alcohol-induced liver disease using urinary metabolomics and the Ppara-null