

lead poisoning prevention practices and recommends improvements in national childhood lead poisoning prevention efforts.

Matter To Be Discussed: Agenda items are subject to change as priorities dictate; however, the current agenda includes:

- Discussion on the potential approaches to strengthen existing strategies to achieve the Healthy People 2010 goal of eliminating elevated blood lead levels as a public health problem in the United States by 2010;
- Update on school performance and concurrent blood lead levels (BLLs);
- Discussion on study designs related to adverse effects from BLLs <10 µg/dL;
- Discussion on the development of a prevention-based research agenda.

Opportunities will be provided during the meeting for oral comments. Depending on the time available and the number of requests, it may be necessary to limit the time for each presenter.

FOR FURTHER INFORMATION CONTACT:

Claudine Johnson, Program Operations Assistant, telephone: 770-488-3629 or Barry Brooks, Administrative Team Leader, telephone: 770-488-3641, Division of Environmental Emergency Health Services, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Hwy, Mailstop F-60, Atlanta, Georgia 30341 telephone: 770-488-3300, fax: 770-488-3635.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 7, 2008.

Daniel Riedford,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. E8-19044 Filed 8-15-08; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 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 Cancer Institute (NCI), the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on June 6, 2008, Volume 73, Number 110, Page 32338 and allowed 60 days for public comment. In response to the notice, there were no public comments received. The purpose of this notice is to allow an additional 30 days for public comment. The 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.

Proposed Collection: Title: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO). *Type of Information Collection Request:* REVISION (OMB #: 0925-0407, current expiry date 10/31/2008). *Need and Use of Information Collection:* This trial is designed to determine if screening for prostate, lung, colorectal and ovarian cancer can reduce mortality from these cancers which currently cause an estimated 254,900 deaths annually in the U.S. 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 through 2008. During the first approval period a pilot study was conducted to evaluate recruitment methods and data collection procedures. Recruitment was completed in 2001 and data collection continues through 2008. When participants enrolled in the trial they agreed to be followed for at least 13 years from the time of enrollment. The current number of respondents in the study is 136, 341; this is down from the total initially due to deaths. The primary endpoint of the trial is cancer-specific mortality for each of the four cancer sites (prostate, lung, colorectum, and ovary). In addition, cancer incidence, stage shift, and case survival are to be monitored to help understand and explain results. Biologic prognostic characteristics of the cancers will be measured and correlated with mortality to determine the mortality predictive value of these intermediate endpoints. Basic demographic data, risk factor data for the four cancer sites and screening history data, as collected from all subjects at baseline, will be used to assure comparability between the screening and control groups and make appropriate adjustments in analysis. Further, demographic and risk factor information may be used to analyze the differential effectiveness of screening in high versus low risk individuals. *Frequency of Response:* Annually. *Affected Public:* Individuals. *Type of Respondents:* Adult men and women. The estimated total annual burden hours requested is 11,401. The annualized cost to respondents is estimated at \$219,919 per year, for a total of \$659,756 over the proposed three year renewal. There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

TABLE A.12-1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (hours)	Total annual burden hours
Male and Female Participants	ASU	133,341.00	1.00	5/60	11,111.75
	HSQ	1,333.33	1.00	5/60	111.08
Male Participants	Prostate	1,066.67	1.00	10/60	177.83
Total					11,400.66

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.

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: Dr. Christine D. Berg, Chief, Early Detection Research Group, National Cancer Institute, NIH, EPN Building, Room 3070, 6130 Executive Boulevard, Bethesda, MD 20892, or call non-toll-free number 301-496-8544 or e-mail your request, including your address to: Bergc@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.

Dated: August 5, 2008.

Vivian Horovitch-Kelley,

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

[FR Doc. E8-18981 Filed 8-19-08; 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.

Extracellular Matrix Gene Chips To Detect Metastatic Tumors

Description of Technology: Cancer mortality is primarily associated with metastatic disease and not the primary tumor. Recent evidence suggests that metastatic disease can be an early event and in the majority of patients metastasis starts by the time the disease is diagnosed. Currently however, approximately one third of patients without evidence of tumor dissemination at the time of surgical resection of the primary tumor subsequently develop distant metastases after the tumor is removed. Therefore there is a need for methods of characterizing the early metastatic process for better treatment of cancer.

This invention provides arrays which can be used for detecting the metastatic capacity of a tumor. In particular, these gene chips or microarrays detect the over-expression of the cancer-related extracellular matrix (ECM) modifier proteins Anakin and Bromodomain 4 (Brd4). It has been shown that ECM gene dysregulation is predictive of metastasis in breast cancer and recently Brd4 and Anakin have been identified as metastasis modifiers.

Using the signature profiles of Anakin and Brd4, the inventors have demonstrated that these genes predict survival outcome in affymetrix and glass slide based microarray experiments. As a result, screening for Brd4 and/or Anakin status in tumors could be an important prognostic test and may enable physicians to better stratify patients based on risk of recurrence and progression to metastatic disease.

Applications:

- Detecting metastatic disease in patients diagnosed with cancer.
- Method of characterizing a tumor or cancer by detecting the expression levels of Anakin or Brd4.
- Diagnostic tool to aid clinicians in determining appropriate cancer treatment.

Market:

- Approximately 1,437,180 new cancer cases are expected to be diagnosed in 2008.
- Almost 565,650 people in the U.S. are expected to die of cancer. This is more than 1,500 people a day.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Kent Hunter and Nigel Crawford (NCI).

Patent Status: U.S. Provisional Application No. 60/970,400 filed 06 Sep

2007 (HHS Reference No. E-093-2007/0-US-01).

Licensing Status: Available for licensing.

Licensing Contact: Whitney A. Hastings; 301-451-7337; hastingw@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute Metastasis Susceptibility Section of the Laboratory of Cancer Biology and Genetics is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Brd4 and/or RRP1B (Anakin) prognostic tests. Please contact John D. Hewes, Ph.D. at 301-435-3121 or hewesj@mail.nih.gov for more information.

NUP98-HOXD13 Transgenic Mice

Description of Technology: Myelodysplastic syndrome (MDS) is collection of closely related blood diseases that arise in the bone marrow characterized by anemia, neutropenia, and thrombocytopenia resulting from hematopoietic stem cell disorders. A variety of genetic aberrations have been associated with MDS, including chromosomal translocations of the NUP98 gene. The only current curative therapy for MDS is allogeneic bone marrow transplant. Without bone marrow transplant, patients either die of progressive pancytopenia or following transformation of MDS to acute myeloid leukemia. Progress in understanding and treating MDS has been hampered by a lack of an animal model that accurately recapitulates all of the features of human MDS. Utilizing a NUP98-HOXD13 (hereafter NHD13) fusion gene, a mouse model was developed to elucidate the biology of MDS. Genetically engineered mice that express an NHD13 transgene display all of the phenotypic features of MDS including peripheral blood cytopenia, bone marrow dysplasia, and transformation to acute leukemia. These mice provide an accurate preclinical model for MDS.

Applications: Model to study MDS and evaluate MDS therapy.

Market: 15,000-20,000 new cases of MDS are diagnosed in the U.S.; 80-90% of patients are older than 60 years old.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Peter D. Aplan *et al.* (NCI).

Publications:

1. YW Lin *et al.* Notch1 mutations are important for leukemic transformation in murine models of precursor-T leukemia/lymphoma. *Blood*. 2006 Mar 15;107(6):2540-2543.