

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 Eddie Billingslea, PhD, Division of Neuroscience, National Institute on Aging, NIH, DHHS, 7201 Wisconsin Avenue, Suite 350, Bethesda, Maryland 20892-9205 or call non-toll-free number 301-496-9350 or e-mail your request, including your address to: billingslea@nia.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: April 11, 2011.

Taryn Ayoub,

Project Clearance Liaison, National Institute on Aging, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (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: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI). **Type of Information Collection Request:** Revision (OMB #: 0925-0407, current expiry date 10/31/2011). **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 254,570 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 2011. 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 2014. 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 122,655; this is down from the initial total due to deaths. The primary

endpoint of the trial is cancer specific mortality for each of the four cancer sites (prostate, lung, colorectal, 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 annual reporting burden is provided for each study component as shown in the Table 1 below. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey instrument	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Male and Female Participants	ASU	92,941	1.00	5/60 (0.08)	7,745
	HSQ	2,000	1.00	5/60 (0.08)	167
	SQX	92,941	1.00	30/60 (0.50)	46,471
Total	54,383

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on 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 Dr. Christine D.

Berg, Chief, Early Detection Research Group, National Cancer Institute, NIH, EPN Building, Room 3100, 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 60 days of the date of this publication.

Dated: April 13, 2011.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

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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.

NAG-1 Transgenic Mouse Model

Description of Technology: The nonsteroidal anti-inflammatory drug-activated gene-1 (NAG-1) encodes a protein that has anti-inflammatory, proapoptotic, and antitumor properties. It plays a pivotal role in antitumorogenesis induced by chemopreventive compounds. Transgenic mice expressing human NAG-1 have been developed by the NIH investigator and collaborator.

The NAG-1 transgenic mice are shown to develop few tumors in response to carcinogenic stimuli than wild type mice. They are also leaner with less fat than their wild type counterparts. As such, these mice can be used to investigate the development of cancers, and they could be of value in studying obesity and the relationship to cancer risk, and inflammation.

Inventors: Thomas E. Eling (NIEHS), *et al.*

Publications:

1. Baek SJ, Okazaki R, Lee SH, Martinez J, Kim JS, Yamaguchi K, Mishina Y, Martin DW, Shoieb A, McEntee MF, Eling TE. Nonsteroidal anti-inflammatory drug activated gene-1 overexpression in transgenic mice suppresses intestinal neoplasia. *Gastroenterology*. 2006 Nov;131(5):1553-1560. [PubMed: 17101328]
2. Cekanova M, Lee SH, Donnell RL, Sukhthankar M, Eling TE, Fischer SM, Baek SJ. Nonsteroidal anti-inflammatory drug-activated gene-1 expression inhibits urethane-induced pulmonary tumorigenesis in transgenic mice. *Cancer Prev Res (Phila)*. 2009 May;2(5):450-458. [PubMed: 19401523]

Patent Status: HHS Reference No. E-093-2011/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing under a Biological Materials License Agreement.

Licensing Contact: Betty B. Tong, PhD; 301-594-6565; tongb@mail.nih.gov.

Collaborative Research Opportunity:

The NIEHS is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Elizabeth M. Denholm, NIEHS Office of Technology Transfer, denholme@niehs.nih.gov, 919-541-0981, for more information.

Altered miRNA Expression as Diagnostics and Therapeutics for Adrenocortical Carcinomas

Description of Technology: This technology describes that altered human miRNA expression such as miRNA-483 and miRNA 100 can accurately predict if a patient's adrenal cortex tumor is benign or malignant. Adrenocortical carcinomas (ACC) are rare but aggressive cancers and typically have a poor prognosis. Currently, there are limited options for molecular diagnosis to distinguish malignant tumors from benign tumors of this type. As a result there are few treatment strategies for ACC.

Additionally, preliminary results suggest that altering the expression of this miRNA in ACC cells can effect cancer cell growth. Therefore, inhibiting a miRNA may serve as a therapeutic option for ACC.

Applications:

- Technology can be developed into a diagnostic and prognostic marker for ACC.
- Inhibiting miRNA can serve as a potential therapeutics for ACC.

Advantages:

- Distinguishes malignant Adrenal cortex tumor from a benign tumor, options for such distinction are limited at this time.

- Technology can help in increased and improved diagnosis and therapeutic options for ACC.

Development Status:

- Pre-clinical.
- Clinical study to test the markers in biopsy and serum samples being planned.

Inventors: Electron Kebebew (CCR, NCI) and Erin E. Patterson (CCR, NCI)

Publication: Patterson E. E. *et al.* (Cancer, 2010). [PubMed: 21061324]

Patent Status: U.S. Provisional Application No. 12/961,298 filed December 6, 2010 (HHS Reference No. E-026-2011/0-US-01)

Licensing Status: Available for licensing.

Licensing Contact: Sabarni Chatterjee, PhD, M.B.A.; 301-435-5587; chatterjeesa@mail.nih.gov

Collaborative Research Opportunity: The Center for Cancer Research, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the use of diagnostic miRNAs and to target these miRNAs for treatment. Please contact John Hewes, PhD at 301-435-3121 or hewes@mail.nih.gov for more information.

Novel Inhibitors of Thymic Stromal Lymphopoietin (TSLP) for Cancer Therapy

Description of Technology: With estimated overall costs in the U.S. in 2006 at \$206.3 billion and WHO predictions of 15 million new cases globally by 2020, the overall economic cost of cancer is staggering. There remains a significant unmet need for therapies to control the spread (metastasis) of cancers to other organs in the body. Available for licensing are compositions and methods of using antagonists of thymic stromal lymphopoietin (TSLP) to prevent cancer progression and metastasis.

TSLP, an IL-7-like type 1 inflammatory cytokine that is often associated with the induction of Th2-type allergic responses in the lungs, is also expressed in cancers regulating their escape (1-3). The cancer-promoting activity of TSLP primarily required signaling through the TSLP receptor on CD4+ T cells, promoting Th2-skewed immune responses and production of immunosuppressive factors such as IL-10 and IL-13. Expression of TSLP therefore may be a useful prognostic marker and its