

Institute (NHLBI), 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: The Cardiovascular Health Study. *Type of Information Request:* Revision. (OMB No. 0925-0334). *Need and Use of Information Collection:* This study will quantify associations between conventional and hypothetical

risk factors and coronary heart disease (CHD) and stroke in people age 65 years and older. The primary objectives include quantifying associations of risk factors with subclinical disease, characterize the natural history of CHD, stroke and identify factors associated with clinical course. The findings will provide important information on cardiovascular disease in an older U.S. population and lead to early treatment of risk factors associated with disease and identification of factors which may be important in disease prevention.

Frequency of Response: twice a year (participants) or once per cardiovascular disease event (proxies and physicians); *Affected Public:* Individuals. *Types of Respondents:* Individuals recruited for CHS and their selected proxies and physicians. The annual reporting burden is as follows: *Estimated Number of Respondents:* 4,606; *Estimated Number of Responses per respondent:* 4.55; and *Estimated Total Annual Burden Hours Requested:* 1,719.

There are no capital, operating, or maintenance costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent*	Average burden hours per response	Estimated total annual burden hours requested
Participants	3,580	5.6	0.25	1,665
Physicians	606	1.0	0.10	20
Participant proxies	420	1.0	0.25	35
Total	4,606	4.55	0.246	1,719

*Total for 3 years.

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) Whether the proposed collection of information will have practical utility; (2) The accuracy of the agency's estimate of burden of the proposed collection of information, 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 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 data collection plans and instruments, contact Dr. Diane Bild, Division of Epidemiology and Clinical Applications, Epidemiology and Biometry Program, NHLBI, NIH, II Rockledge Centre, 6701 Rockledge Drive, MSC 7934, Bethesda, MD 20892-7934, or call non-toll-free number (301) 435-0707, or e-mail your request, including your address to: bild@nih.gov.

DATES: *Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received on or before February 2, 2001.

Dated: November 16, 2000.

Peter Savage,
Acting Director, Division of Epidemiology and Clinical Applications, National Heart, Lung, and Blood Institute.

[FR Doc. 00-30713 Filed 12-1-00; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, Public Health Service, DHHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by agencies 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: A Non-Steroidal Anti-Inflammatory Drug Related Gene Which Has Anti-Tumorigenic Properties

Thomas E. Eling, Seung Joon Baek (NIEHS)
DHHS Reference No. E-170-00/0 filed 08 Sep 2000
Licensing Contact: Richard Rodriguez; 301/496-7056 ext. 287; e-mail: rodrigur@od.nih.gov
Non-steroidal anti-inflammatory drugs (NSAIDs) are widely used in the treatment of inflammatory disease, and their anti-inflammatory effects are believed to result from their ability to inhibit the formation of prostaglandins by prostaglandin H synthase (COX). Two forms of prostaglandin H have been identified, COX-1 and COX-2. The former seems to be constitutively expressed in a variety of tissues while the high expression of the latter has been reported in colorectal tumors. NSAIDs have been shown to be effective in reducing human colorectal cancers and possibly breast and lung cancers. While the exact mechanism(s) by which NSAIDs function has not been elucidated, they could potentially play a critical role in detecting, diagnosing and treating inflammatory diseases as well as cancer. The present invention relates to screening methods for the identification of agonistic and/or antagonistic agents for the activation of the promoter region of NAG-1. Additional claims are directed to 1) the

DNA sequence of NAG-1, 2) compositions containing the NAG-1 sequence and 3) methods for treating cancer patients using NAG-1.

Novel MHC Class II Restricted T Cell Epitopes from the Cancer Antigen, NY-ESO-1

DHHS Reference No. E-090-00/0 filed 28 Jan 2000 and

MHC Class II Restricted CD4+ T Cell Epitopes From NY-ESO-1 Presented by DP

DHHS Reference No. E-227-00/0 filed 29 Sep 2000

Wang et al. (NCI)

Licensing Contact: Elaine White; 301/496-7056 ext. 282; e-mail: gesee@od.nih.gov

NY-ESO-1 is a known tumor antigen which is expressed on a broad range of tumor types, including melanoma, breast, bladder, ovarian, prostate, head and neck cancers, neuroblastoma, and small cell lung cancer. The above-referenced inventions embody the identification of a number of novel immunogenic peptide epitopes, and analogs thereof, which are derived from the NY-ESO-1 tumor antigen.

DHHS Reference No. E-090-00/0 serves to identify novel MHC Class II restricted epitopes of NY-ESO-1 which are recognized by CD4+ T cells. DHHS Reference No. E-227-00/0 embodies the identification of two additional immunogenic peptide epitopes of NY-ESO-1. The latter two epitopes are presented by HLA-DP4, a prevalent MHC Class II allele present in 43-70% of Caucasians. The inventors also determined that the DP allele is highly associated with the NY-ESO-1 antibody production. In addition, one of these epitopes has dual HLA A2 and DP4 specificity, thereby has the potential to generate both CD4+ and CD8+ tumor specific T cells. These epitopes may be of great value as prophylactic and/or therapeutic cancer vaccines for use against a number of common cancers.

T-Cell Epitope of MAGE-12 and Related Nucleic Acids, Vectors, Cells, Compositions, and Methods of Inducing an Immune Response to Cancer

Monica Panelli, Francesco Marincola, Maria Bettinotti (NCI)
DHHS Reference No. E-056-00/0 filed 03 Mar 2000

Licensing Contact: Elaine White; 301/496-7056 ext. 282; e-mail: gesee@od.nih.gov

The current invention embodies the identification of a T-cell epitope from the cancer-specific antigen MAGE-12. The MAGE family of genes encodes human tumor specific antigens (TSA),

and various genes of this family are expressed by tumors of different histologies (melanoma, lung, colon, breast, laryngeal cancer, sarcomas, certain leukemias) and not by normal cells (except testis and placenta). The MAGE-12 peptide which is the subject of the current invention is a specific epitope within MAGE-12 (residues 170-178) which is recognized by tumor infiltrating lymphocytes in the context of HLA-Cw0702 (a common HLA type in the Caucasian population). This T-cell epitope is advantageous in that it represents a novel tumor rejection antigen for use as a peptide vaccine against melanoma or other cancer types expressing MAGE-12 and may therefore be of great value for use in cancer immunotherapy.

Secreted Frizzled Related Protein, sFRP, Fragments and Methods of Use Thereof

JS Rubin, A Uren (both of NCI), and F Reichsman, S Cumberledge

Serial No. 09/546,043 filed 10 April 00

Licensing Contact: Susan S. Rucker; 301/496-7056 ext 245; e-mail: ruckers@od.nih.gov

This application relates to signal transduction pathways and mechanisms. More particularly, the application describes various active fragments of the secreted Wnt binding protein sFRP-1 (secreted Frizzled Related Protein-1). The sFRP-1 fragments described are capable of binding to Wnt and therefore are able to modulate Wnt activity. The fragments may or may not contain the cysteine rich domain (CRD) of sFRP-1 suggesting that the CRD is not essential for Wnt binding. In addition, in contrast to earlier findings employing higher levels of sFRP-1, the ability of sFRP-1 to enhance Wnt signaling at low levels is also described suggesting biphasic regulation of Wnt signaling by sFRP-1. The sFRP-1 fragments described herein may be useful in the further study of Wnt signaling as well as targets for the development of small molecules which can modulate Wnt signaling. PHS also owns additional intellectual property related to sFRP-1 which is described in US Patent Application Serial Number 09/087,031 and which has been published as WO 98/54325 (12/03/1998).

This work has appeared, in part, in Uren, A et al. JBC 275(6): 4374-4382 (Feb 11, 2000).

Dated: November 22, 2000.

Jack Spiegel,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 00-30714 Filed 12-1-00; 8:45 am]

BILLING CODE 4140-01-P

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ADDRESSES: Licensing information and a copy of the U.S. patent application referenced below may be obtained by contacting J. R. Dixon, Ph.D., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 (telephone 301/496-7056 ext 206; fax 301/402-0220; e-mail: jd212g@nih.gov). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

Entitled: "Discovery of Gene Expressed in Many Cancers and Only Normal Testis"

Inventors: Drs. Ira H. Pastan (NCI), Xiu F. Liu (NCI), Byungkook Lee (NCI) and Lee J. Helman (NCI).

DHHS Ref. No. E-161-00/0 Filed: September 1, 2000.

Large numbers of expressed sequence tags (EST's) have been cloned from various normal and cancer tissues. Cancer-testis antigens are a distinct class of differentiation antigens that have a restricted pattern of expression in normal tissues. These genes are primarily expressed in the primitive germ cells, spermatogonia, in the normal testis. Malignant transformation is often associated with activation or derepression of silent Cancer-testis genes, and this results in the expression of Cancer-testis antigen in a variable proportion of a wide range of human tumors. Three related genes, termed XAGEs, were recently identified by homology walking using the dbEST database.

The XAGE-1 gene is a human X-linked gene that is strongly expressed in