survey will be one source of input into a statutorily mandated assessment and report to the Congress on special funding for research on type 1 diabetes provided by the Balanced Budget Act of 1997, (Pub. L. 105–33), the FY 2001 Consolidated Appropriations Act, (Pub. L. 106–554), and the Public Health Service Act Amendment for Diabetes, (Pub. L. 107–360). Collectively, these Acts provided $1.14 billion in special funds to the Department of Health and Human Services (HHS) for research aimed at understanding, treating and preventing type 1 diabetes and its complications. The Secretary of HHS subsequently designated to NIDDK the lead responsibility in the Department for developing a process for allocation of these funds. The primary objective of the survey is to gain information, via a brief questionnaire, from NIH research grantees, who were the primary recipients of these special funds, concerning their views on the impact of the type 1 diabetes research funding with respect to: (1) Advancing scientific accomplishments involving innovative, clinically relevant, and multidisciplinary research on type 1 diabetes; (2) developing resources or reagents useful for type 1 diabetes research; and (3) increasing the number and quality of type 1 diabetes investigators. The responses will provide valuable information concerning how the funds have facilitated research as intended by these Acts of Congress. The results will also help determine how research progress from these special congressional initiatives fits within the continuum of diabetes research, and how these funds have contributed to the field of type 1 diabetes research and NIH efforts to combat this challenging health problem. Information from this study will aid in evaluation of the process by which the research goals for use of the special type 1 diabetes funds have been developed and are being pursued. Responses already collected from this survey were analyzed as part of an interim program assessment that was published by the NIDDK in April, 2003 *http://www.niddk.nih.gov/federal/planning/type 1_specialfund/.* This revised survey will contribute to a statutorily mandated report, due to Congress on January 1, 2007, evaluating the process and efforts under this program and assessing research initiatives funded by these Acts of Congress.

Frequency of Response: The initial survey will require a one time response; though, respondents may be contacted again in the event of future congressionally mandated reports on the use of the special type 1 diabetes research funds.

Affected Public: Research scientists who received the special funds about which Congress has mandated in law the requirements for an evaluation report. *Type of Respondents:* Laboratory and clinical investigators who have received support from the special type 1 diabetes funds provided under the laws previously cited. The annual reporting burden is as follows: *Estimated Number of Respondents:* 500; *Estimated Number of Responses per Respondent:* 1 (Respondents will be given one questionnaire containing an estimated fifteen questions.); *Average Burden Hours Per Response:* 1; and *Estimated Total Annual Burden Hours Requested:* 500. The annualized total cost to respondents is estimated at: $25,000. It is expected that the respondents will be contacted vie e-mail and that their responses will be collected through an Internet-accessible questionnaire. These measures will reduce the burden on the respondents and the overall costs of administering the study. Because different types of awards have been made with the special type 1 diabetes funds, the questionnaire may be tailored such that respondents will only be asked to answer a subset of questions that pertain to their particular type of award(s). No respondent will be asked to answer more than a total of fifteen questions, at least one-third of which will be answered with a ''yes'' or ''no'' or a one-word response. There are no Capital Costs, Operating or Maintenance Costs to report.

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 is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) 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) 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.

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. Shefa Gordon, Office of Scientific Program and Policy Analysis, NIDDK, NIH, Building 31, Room 9A31, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number 301–496–6623 or e-mail your request, including your address to: *gordonshefa@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: March 2, 2005.

Lynell Nelson,

Project Clearance Liaison, NIDDK, National Institutes of Health.

[FR Doc. 05–4674 Filed 3–9–05; 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, 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.

Dimer Inhibitory Peptides of CXCR4 as a Possible Novel Therapy for Cancer

Jinhai Wang and Michael Norcross (FDA),
DHHS Reference No. E–037–2005/0—Research Tool,
Licensing Contact: John Stansberry; (301) 435–5236; *stansbej@mail.nih.gov.*

This invention may control or inhibit cancer metastases by targeting

chemokine receptor dimer formation. Specifically, this invention relates to a synthetic peptide of the transmembrane region 4 (TM4) of the Chemokine receptor (CXCR4). TM4 inhibits CXCR4 dimerization and tumor cell migration. CXCR4 is highly expressed in human breast cancer cells, prostate cancer, and pancreatic cancer. CXCR4 is involved in breast cancer metastasis and tumor migration. Immunotherapies or vaccinations based on blocking chemokine receptor dimerization with TM4 could be a useful treatment against proliferative diseases and cancer.

Carbohydrate-Encapsulated Gold Nanoparticles as Novel Anti-metastatic Agents

Drs. Joseph Barchi (NCI), Sergei Svarovsky (NCI) *et al.,*
DHHS Reference No. E–001–2005/0–PCT–01,
Licensing Contact: John Stansberry; (301) 435–5236; *stansbej@mail.nih.gov.*

The invention relates to the development of a new synthesis for the tumor-associated, cell-surface carbohydrate moiety, known as the Thomsen-Friedenrich T antigen. The inventors prepared a novel, multivalent presentation platform by linking this disaccharide antigen to the surface of gold nanoparticles and describe the application of the multivalent system as an anti-adhesive tool to inhibit metastasis. The glyconanoparticles principle described here has the potential to integrate all the current knowledge and applications on processes that involve carbohydrate molecules (inflammation, viral, bacterial, and toxin infection, etc.). Administration of these nanoparticles into mice bearing breast tumors was shown to inhibit lung metastases in this model. This technology establishes the ''proof of principle'' for possible biological applications of glyconanoparticles.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

Methods for the Selection of Subjects for Multiple Sclerosis Therapy

Roland Martin *et al.* (NINDS),
International Application No. PCT/US04/10584 filed 05 Apr 2004 (DHHS Reference No. E–005–2004/0–PCT–01),
Licensing Contact: Thomas Clouse; (301) 435–4076; *clousetp@mail.nih.gov.*

Multiple Sclerosis (MS) is a life-long chronic autoimmune disease diagnosed primarily in young adults who have a virtually normal life expectancy. Estimates place the annual costs of MS in the United States in excess of $2.5 billion. There are approximately 250,000 to 400,000 persons in the United States with MS, and approximately 2.5 million persons worldwide suffer from MS. A variety of therapies are used to treat MS, but there is no single therapy that can be used to treat all patients. Furthermore, therapies that are currently approved for MS are only moderately effective, and in some patients they have no effect at all. The invention provides a method to determine if a patient with MS will respond to a therapeutic protocol by analyzing the expression of genes expressed by the immune system. For example, a single gene can be assessed, or an expression profile of a patient can be created using an array comprising gene sequences and analyzed to determine if the patient will respond to one or more therapeutic protocols. A cDNA probe constructed from mRNA of lymphocytes isolated from a patient can hybridize with a microarray, and the extent of hybridization of the probes to each gene on the microarray can be determined. The microarray can include nucleic acid sequences encoding, for example, IL–8, Bcl–2–interacting protein, dihydrofolate reductase, gyanylate-binding protein 1, interferon-induced 17 kDa protein, 2′5′ OAS, plakoglobin, interferon inducible proteinkinase, and STAT–1, among others.

Methods for Identifying, Diagnosing, and Predicting Survival of Lymphomas

Louis M. Staudt *et al.* (NCI),
PCT Application No. PCT/US2004/029041 filed 03 Sep 2004 (DHHS Reference No. E–234–2003/1–PCT–01) and U.S. Non-Provisional Patent Application 10/934,930 filed on 03 Sep 2004 (DHHS Reference No. E–108–2004/0–US–01),
Licensing Contact: Jeff Walenta; (301) 435–4633; *walentaj@mail.nih.gov.*

Human lymphomas and leukemias are a diverse set of cancers. Many of these cancers, while expressing a similar phenotype between different individuals, have a diverse underlying genetic basis for the disease. This diverse genetic basis has implications on the effective treatment of the various phenotypes of lymphoma. For example, a drug that was effective against one individual's phenotype of lymphoma will not be effective against a similar lymphoma in another individual. An invention that helps clinicians classify a lymphoproliferative disorder would provide the basis for a ''pharmacogenomic'' method for treating such cancers.

The present invention discloses a novel microarray for obtaining gene expression profile data to be used in identifying lymphoma types and predicting survival in a lymphoma patient. The present invention further discloses a variety of methods for analyzing gene expression data obtained from a lymphoma sample, and specific algorithms for predicting survival and clinical outcome in a subject suffering from a lymphoma. The gene expression profile data set was established using a human genome gene chip set measuring the expression of over 27,000 genes in more than 500 lymphoproliferative tumor samples collected from patients at numerous healthcare institutions worldwide.

This invention could be developed into a useful pharmacogenomic, diagnostic product. The number of genes required for an accurate prognosis is reduced almost ten-fold from the human genome gene chip, allowing for lower density microarray technology and alternative gene expression measuring platforms. The choice of the gene set in this invention is optimized to provide an all in one method for the diagnosis of all lymphomas.

In addition to licensing, the technology is available for further development through collaborative research with the inventors via a Cooperative Research and Development Agreement (CRADA).

HGC–1, a Gene Encoding a Member of the Olfactomedin-Related Protein Family

Griffin P. Rodgers, Wen-Li Liu, Jiachang Zhang (NIDDK),
U.S. Provisional Patent Application 60/338,759 filed 07 Dec 2001 (DHHS Reference No. E–166–2001/0–US–01); PCT Application No. PCT/US02/39148 filed 09 Dec 2002, which published as WO 03/050293 on 19 Jun 2003 (DHHS Reference No. E–166–2001/0–PCT–02),
Licensing Contact: Brenda Hefti; (301) 435–4632; *heftib@mail.nih.gov.*

The current technology embodies a newly identified gene, Human Granulocyte Colony-Stimulating Factor-Stimulated-Clone-1 (hGC–1) that has been cloned and characterized, and its protein sequence has been deduced. The gene is expressed in the bone marrow, prostate, small intestine, colon, and stomach, and has been mapped to chromosome 13 in a region that contains a tumor suppressor gene cluster. The gene is found to be selectively present

in normal human myeloid lineage cells and is believed to play a role in allowing lymphocytes to differentiate properly. It is believed that the gene may play a role in human prostate cancer, multiple myeloma, B-cell chronic lymphocytic leukemia and other types of cancer and can be used diagnostically as well as in therapeutic screening activities.

Tyrosyl-DNA Phosphodiesterases (TDP) and Related Polypeptides, Nucleic Acids, Vectors, TDP-Producing Host Cell, Antibodies and Methods of Use

Jeffrey J. Pouliot and Howard A. Nash (NIMH),

U.S. Patent Application No. 10/110,176 filed 05 Apr 2002 (DHHS Reference No. E–281–1999/0–US–03), claiming priority to U.S. Provisional Application No. 60/157,690 filed 05 Oct 1999 (DHHS Reference No. E–281–1999/0–US–01),

Licensing Contact: John Stansberry; (301) 451–7337; *stansbej@mail.nih.gov.*

Topisomerases are cellular enzymes that are vital for replication of the genome. However, if topisomerase and DNA form covalent complexes that prevent the resealing of DNA, this may lead to cell death. Essentially, this invention consists of a new isolated and cloned enzyme, tyrosyl-DNA phospodiesterase (TDP1) that is capable of hydrolyzing the covalent complexes between topisomerase and DNA, allowing the DNA to reseal. The mechanism that defines topiosomerases is their capacity to break DNA and, after an interval in which topological changes may occur, to reseal the break without the intervention of a high-energy cofactor. The breakage of the DNA is accompanied by the formation of a covalent bond between topisomerase and DNA to create an intermediate that is resolved during the resealing step. However, if the resealing step fails, the covalent intermediates between topoisomerase I and DNA can form complexes that lead to cell death. The failure of the resealing is increased by some chemotherapies such as camptothecin. Thus, this technology has many potential commercial uses including: a method for screening camptothecin analogues or other compounds for their resistance to repair by this enzyme or to prescreen patients for their sensitivity to topoisomerase inhibitors, which could identify patients most likely to respond to camptothecin therapy. Further, this invention provides for a vector comprising of the nucleic acid molecule for TDP1 as well as the method of altering the level of TDP1 in a cell, a tissue, an organ or an organism. Finally, this invention consists of a method for identifying a compound that stabilizes a covalent bond complex that forms between DNA and topoisomerase I, wherein the covalent bond cannot be cleaved.

Chromatin Insulator Protecting Expressed Genes of Interest for Human Gene Therapy or Other Mammalian Transgenic Systems

Drs. Jay H. Chung and Gary Felsenfeld (NIDDK),

U.S. Patent 5,610,053 issued 11 Mar 1997 (DHHS Reference No. E–206–1992/1–US–01), Licensing Contact: John Stansberry; (301) 435–5236; *stansbej@mail.nih.gov.*

The technology provides the isolation of a functional DNA sequence comprising a chromatin insulating element from a vertebrate system and provides the first employment of the pure insulator element as a functional insulator in mammalian cells. The technology further relates to a method for insulating the expression of a gene from the activity of cis-acting regulatory sequences in eukaryotic chromatin.

This technology could be of major importance in providing a mechanism and a tool to restrict the action of cis-acting regulatory elements on genes whose activities or encoded products are needed or desired to be expressed in mammalian transgenic systems. This technology provides the first pure insulator element to function solely as an insulator element in human cells. Accordingly, this technology could have tremendous practical implications for transgenic technology and human gene therapies, either *in vitro* or *in vivo*.

The technology further provides a method and constructs for insulating the expression of a gene or genes in transgenic animals such that the transfected genes will be protected and stably expressed in the tissues of the transgenic animal or its offspring. For example, even if the DNA of the construct integrates into areas of silent chromatin in the genomic DNA of the host animal, the gene will continue to be expressed. The invention could provide a means of improving the stable integration and expression of any transgenic construct of interest, with efficiencies higher than are achieved presently. Use of this invention may represent a large potential savings for licensee's constructing transgenic cell lines or animals.

Dated: March 2, 2005.

Steven M. Ferguson,

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

[FR Doc. 05–4675 Filed 3–9–05; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 05–59, Review F30s.

Date: March 30, 2005.

Time: 2 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Lynn M. King, PhD, Scientific Review Administrator, Scientific Review Branch, 45 Center Dr., Rm 4AN–38K, National Institute of Dental & Craniofacial Research, National Institutes of Health, Bethesda, MD 20892–6402, (301) 594–5006.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 05–55, Review of R21s.

Date: April 11, 2005.

Time: 11 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Rebecca Roper, MS, MPH, Scientific Review Administrator, Scientific Review Branch, Division of Extramural Research, National Inst of Dental & Craniofacial Research, National Institutes of Health, 45 Center Dr., room 4AN32E, Bethesda, MD 20892, (301) 451–5096.

Name of Committee: National Institute of Dental and Craniofacial Research Special Emphasis Panel, 05–56, Review R21s.