Electronic comments or submissions will be accepted by FDA only at *http://www.regulations.gov*.

Dated: April 30, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–10555 Filed 5–6–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NHLBI Health Information Center's Revolving Customer Satisfaction Survey

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 Heart, Lung and Blood 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: NHLBI Health Information Center's Revolving Customer Satisfaction Survey. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The purpose of this survey is to identify those areas in which services provided by the NHLBI Health Information Center (HIC) to health professionals, patients and their families, and the general public are outstanding and areas where improvements are needed. That information will be used to formulate programs, processes, training, and enhancements to raise the level of customer satisfaction with the services provided by the NHLBI HIC. With subsequent surveys, data will demonstrate whether gains have been made in areas for improvement and if new customer needs must be addressed. *Frequency of Response:* Twice a year. *Affected Public:* Individuals. *Type of Respondents:* Individuals who contact the NHLBI HIC by telephone or e-mail during each 1-month data collection period. The annual reporting burden is as follows: *Estimated Number of Respondents:* 99; *Estimated Number of Responses per Respondent:* 1; *Average Burden Hours per Response:* 0.05; and *Estimated Total Annual Burden Hours Requested:* 9.9. The annualized cost to respondents is estimated at: $242.15. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondent	Estimated number of respondents	Annual frequency of response	Average burden hours per response	Estimated total annual burden hours requested
General Public	43	2	0.05	4.3
Private Companies	14	2	0.05	1.4
Public Sector Groups	13	2	0.05	1.3
Health Professionals	29	2	0.05	2.9
Totals	99			9.9

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. Ann M. Taubenheim, Principal Investigator, National Heart, Lung, and Blood Institute, Office of Communications and Legislative Activities, NIH, 31 Center Drive, Building 31, Room 4A10, Bethesda, MD 21045, or call non-toll-free number 301–496–4236 or e-mail your request, including your address, to *taubenha@nhlbi.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 28, 2009.

Ann M. Taubenheim,

Principal Investigator, NHLBI.

[FR Doc. E9–10586 Filed 5–6–09; 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.

Novel Inhibitors of Bone Morphogenetic Proteins

Description of Technology: Bone Morphogenetic Proteins (BMPs) are signaling molecules that are central in a variety of biological processes, but were first recognized for their role in inducing bone and cartilage development. Abnormal BMP signaling has been implicated in the pathogenesis of a class of joint disorders known as spondyloarthropathies which includes

ankylosing spondylitis, psoriatic arthritis, reactive arthritis, and arthritis associated with inflammatory bowel disease. Therefore, inhibitors and modulators of BMP signaling may be useful in managing these disorders. Moreover, the BMPs and their antagonists have now been implicated in myriad cell and tissue differentiation and fate specification processes, extending their utility far beyond orthopedic and rheumatologic applications. Scientists at the Food and Drug Administration, National Institutes of Health and Katholieke Universiteit Leuven have discovered a novel inhibitor of BMPs called Secreted Modular Calcium Binding protein (SMOC) which is unrelated to known BMP inhibitors.

This technology relates to a method for treating disorders including joint disorders by administering a SMOC polypeptide to induce intracellular mitogen activated protein (MAP) kinase activity to effect a reduction of BMP signaling activity in the cells of a patient. It also encompasses methods to manipulate differentiation processes regulated by BMPs. One prominent example is the specification of neural, as opposed to epithelial, cell fate.

Applications

- Treatment of joint diseases.
- Manipulation of tissue fate specification *in vitro*, alone or in combination with other materials, in production of therapeutic cells and tissues.

Advantages

- Ability to interrupt BMP signaling by a novel mechanism;
- Predictable synergy with other BMP antagonists;
- No indication of being immunosuppressive;
- In some instances SMOC is associated with extracellular matrix molecules, allowing for spatially restricted BMP antagonism not possible with diffusible factors such as noggin.

Development Status: Early stage.

Market: Modulation of BMP signaling by secreted inhibitors is involved in formation of the body axis, limbs and joints, all organs, and nervous tissue, to name a few. The applications of SMOC in conjunction with other growth factors *in vitro* in various developmental programs to produce therapeutic cells and/or tissues are therefore numerous. In addition, BMPs are involved in many disorders in man, and modulating their activities may provide a therapeutic benefit for a number of diseases and disorders such as arthritis and spondyloarthropathies.

Inventors: Malcolm C. Moos *et al.* (CBER/FDA), Frank P. Luyten (NIDCR).

Publications: None related to this invention.

Patent Status: U.S. Provisional Application No. 61/086,679 filed 06 Aug 2008 (HHS Reference No. E–338–2005/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Surekha Vathyam, PhD; 301–435–4076; *vathyams@mail.nih.gov*.

Salcut-NH2: A Novel Target for Development of Anti-Tumorigenic, Anti-Angiogenic Therapeutics and Diagnostics

Description of Technology: Salcut-NH2, a novel amidated peptide derived from the Apelin proprotein, is shown to induce the proliferation of cells. Uncontrolled cell proliferation is the salient feature of cancer. Thus, therapeutics that stop this aberrant cell division are very desirable. Salcut-NH2 can be the basis for developing novel inhibitors of cancer growth such as modified peptide antagonists like salcut-glycine (salcut-Gly). Alternately, salcut-NH2 could be the target of antibody therapies that block its activity. In some instances, such as wound healing, inducing cell proliferation would be advantageous. It also has been demonstrated that salcut-NH2 induces angiogenesis so it may also have application as a topically administered therapeutic for speeding the healing of skin wounds. Finally, increasing levels of salcut-NH2 in body fluids may be reflective of disease progression. A diagnostic kit for salcut-NH2 could potentially be developed for the prognosis of a variety of diseases associated with aberrant cell proliferation or angiogenesis.

Applications

- Development of therapeutics that inhibit cancer growth or diseases related to aberrant angiogenesis.
- Topical therapeutic to hasten wound healing.
- Diagnostic for the prognosis of cancer or diseases related to aberrant growth of blood vessels.

Advantages

- Naturally derived peptide and thus negligible immunogenicity.
- Amidation makes salcut-NH2 resistant to proteases and increases its availability.
- Small peptides are readily excreted facilitating measurement of salcut-NH2 for diagnostic purposes.

Development Status: Early stage; pre-clinical data available.

Markets:

- Cancer is the second most common cause of death in the U.S., exceeded only by heart disease. In the U.S., cancer accounts for 1 of every 4 deaths and more than 2.4 million new cancer cases were expected to be diagnosed in 2008.
- Age-related macular degeneration (AMD) is a degenerative disease of the retina that eventually leads to a loss of vision. The wet form of AMD is the most common and is characterized by the abnormal growth of retina blood vessels and results in a rapid loss of central vision. It is estimated that AMD affects 1.75 million people in the United States.

Inventors: Frank Cuttitta *et al.* (NCI).

Publications: None related to this invention.

Patent Status: U.S. Provisional Application No. 61/156,351 filed 27 Feb 2009 (HHS Reference No. E–179–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Surekha Vathyam, PhD; 301–435–4076; *vathyams@mail.nih.gov*.

Collaborative Research Opportunity: The National Cancer Institute Angiogenesis Core Facility is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize (1) Identification of new biological functions for Salcut-NH2 or (2) Development of compounds that suppress or augment Salcut-NH2 bioactivity. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Novel Oligonucleotides for Treatment of Human Cancer

Description of Technology: Human endogenous retroviruses (HERVs) are remnants of retroviruses that invaded and integrated into the human genome 6–15 million years ago. One significant type of HERV is ERV–9; approximately 5% of the total human genome comprises sequences from this retrovirus family. The human genome contains approximately 50 copies of ERV–9 along with 3000–4000 copies of solitary elements of ERV–9 regulatory regions, called long terminal repeats (LTRs). The solitary LTRs contain promoter and enhancer elements that drive expression of genes located proximally to the LTR. Therefore, insertion of an ERV–9 LTR proximal to an oncogene could initiate carcinogenesis.

This invention relates to the use of antisense and sense oligonucleotides (oligos) targeting the RNAs of ERV–9

LTR as a treatment for various cancers, including human breast, liver, prostate, and myeloid cancers and fibrosarcomas. The inventors have shown that the ERV–9 LTR sense and antisense oligos can inhibit cancer cell proliferation *in vitro* more efficiently than the antisense oligos of Bcl-2 (G3139) and telomerase (GRN163), both of which are currently in cancer clinical trials. The oligos have minimal effects on the proliferation of primary normal human cells *in vitro.* These oligos have potential as a new therapeutic agent to suppress tumor cell growth, either when used alone or in conjunction with other antisense oligos or with chemotherapeutic agents such as VePesid. Furthermore, sense and antisense RNA transcripts of ERV–9 LTR were detected in many human normal and tumor cells in this invention. The sense and antisense RNA may form double stranded RNA and act as siRNA to regulate gene expression.

Applications

• Therapeutic oligos of the invention can be used to treat variety of cancers including, but not limited to, breast, liver, myeloid and prostate cancers and fibrosarcomas.

• The oligos can be used either singly or as adjuvant therapy with chemotherapeutic agents.

• ERV–9 LTR related cancers can be diagnosed by comparative analysis of the levels of ERV–9 LTR RNAs in tumors versus those of healthy tissues.

Advantages

• Greater inhibition of cell proliferation by oligos of the invention compared to the Bcl-2, telomerase and MDM2-specific antisense oligos which are currently in development as cancer therapies.

• The therapeutic effect of the oligos is specific for cancer cells as the oligos do not significantly alter proliferation of normal human cells.

Development Status: In vivo testing of therapeutic sense and antisense oligos in mouse xenograft models has been successfully conducted.

Market: Cancer is the second leading cause of death in the United States. More than 1 million Americans are diagnosed with cancer each year.

Inventors: Lai Xu (FDA/CDER), Abdel Elkahloun (NHGRI), Fabio Candotti (NHGRI), Amy Rosenberg. (FDA/CDER)

Publications: None related to invention have been published.

Patent Status: U.S. Provisional Application No. 61/191,911 filed 11 Sep 2008 (HHS Reference No. E–092–2008/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Surekha Vathyam, PhD; 301–435–4076; *vathyams@mail.nih.gov*.

Dated: April 30, 2009.

Richard U. Rodriguez,

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

[FR Doc. E9–10549 Filed 5–6–09; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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: Center for Scientific Review Special Emphasis Panel; Cancer Pathobiology ARRA CR.

Date: May 19, 2009.

Time: 2 p.m. to 6 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Elaine Sierra-Rivera, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7804, Bethesda, MD 20892. 301–435–1779. *riverase@csr.nih.gov.*

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Biological Chemistry and Macromolecular Biophysics; Integrated Review Group, Biochemistry and Biophysics of Membranes Study Section.

Date: May 28–29, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Dupont Hotel, 1500 New Hampshire Avenue, NW., Washington, DC 20036.

Contact Person: Nuria E. Assa-Munt, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4164, MSC 7806, Bethesda, MD 20892, (301) 451–1323, *assamunu@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics; Integrated Review Group, Macromolecular Structure and Function—B Study Section.

Date: May 28–29, 2009.

Time: 8 a.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street, NW., Washington, DC 20037.

Contact Person: Arnold Revzin, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4146, MSC 7824, Bethesda, MD 20892, (301) 435–1153, *revzina@csr.nih.gov.*

Name of Committee: Immunology Integrated Review Group; Cellular and Molecular Immunology—A Study Section.

Date: May 28–29, 2009.

Time: 8:30 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Crystal City, 2399 Jefferson Davis Highway, Arlington, VA 22202.

Contact Person: Samuel C. Edwards, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4200, MSC 7812, Bethesda, MD 20892. (301) 435–1152. *edwardss@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Bioengineering Member Conflicts.

Date: May 29, 2009.

Time: 10 a.m. to 11 a.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Ping Fan, MD, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5154, MSC 7840, Bethesda, MD 20892. 301–435–1740. *fanp@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 30, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–10529 Filed 5–6–09; 8:45 am]

BILLING CODE 4140–01–M