

Type of respondents	Estimated number of respondents	Estimated number of responses per respondents	Average burden hours per response	Estimated total annual burden hours requested
Next-of-kin .....	2,741	1	.0835	229
Physician's Office Staff .....	226	1	.0835	19
Total .....				36,467

The annualized cost burden to respondents is estimated at \$365,428. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

**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 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology permitting electronic submission of responses.

**DIRECT COMMENTS TO OMB:** Written comments and/or suggestions regarding item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to: The Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plan and instruments, contact: Dr. Linda Pottern, Project Officer, Women's Health Initiative Program Office, 6705 Rockledge Drive, 1 Rockledge Centre, Suite 300, MSC 7966, Bethesda, MD 20892-7966, or call (301) 402-2900 or E-Mail your request, including your address to: Linda\_Pottern@nih.gov

**COMMENTS DUE DATE:** Comments regarding this information collection are best assured of having their full effect if received on or before June 2, 2000.

Dated: March 20, 2000.

**Jacques E. Rossouw,**  
*Acting Director, Women's Health Initiative, NHLBI.*

[FR Doc. 00-8104 Filed 3-31-00; 8:45 am]

**BILLING CODE 4140-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Government-Owned Invention; Availability for Licensing: "Therapeutic Method to Treat Cancer and Define Cellular Regulatory Processes—Transcription Factor Decoy and Tumor Growth Factor"**

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

**ACTION:** Notice.

**SUMMARY:** The invention listed below is owned by an agency of the U.S. Government and is 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.

**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.

**SUPPLEMENTARY INFORMATION:** *Invention Title:* "Transcription Factor Decoy and Tumor Growth Inhibitor".

*Inventors:* Dr. Yoon S. Cho-Chung (NCI).

*USPA SN:* 08/977,643 [= DHHS Ref. No. E-192-97/0]—Filed with the U.S.P.T.O. on November 24, 1997.

*Technology:* Alteration of gene transcription by inhibition of specific transcriptional regulatory proteins has important therapeutic potential. Synthetic double-stranded phosphorothioate oligonucleotides with high affinity for a target transcription factor can be introduced into cells as

decoy cis-elements to bind the factors and alter gene expression. The CRE (cyclic AMP response element)-transcription factor complex is a pleiotropic activator that participates in the induction of a wide variety of cellular and viral genes. Because the CRE cis-element, TGACGTC, is palindromic, a synthetic single-stranded oligonucleotide composed of the CRE sequence self-hybridizes to form a duplex/hairpin. The CRE-palindromic oligonucleotide can penetrate into cells, compete with CRE enhancers for binding transcription factors, and specifically interfere with CRE- and AP-1-directed transcription *in vivo*. These oligonucleotides restrained tumor cell proliferation, without affecting the growth of noncancerous cells. This decoy oligonucleotide approach offers great promise as a tool for defining cellular regulatory processes and treating cancer and other diseases. [see J. Biol. Chem. 274, 1573-1580 (1999); online at <http://www.jbc.org/>]

The above mentioned Invention is available, including any available foreign intellectual property rights, for licensing.

Dated: March 24, 2000.

**Jack Spiegel,**  
*Director, Division of Technology Development & Transfer, Office of Technology Transfer*  
[FR Doc. 00-8106 Filed 3-31-00; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Opportunity for Licensing: Adenovirus Mediated Transfer of Genes**

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

**ACTION:** Notice.

**SUMMARY:** The National Institutes of Health (NIH), Public Health Service (PHS), Department of Health and Human Services (DHHS), seeks a licensee(s) to develop gene therapy-based therapeutics that would be effective in the treatment of a variety of disease states, particularly via transfer of specific genes to the lung. The inventors have developed adenoviral

vectors and pharmaceutical compositions comprising (a) a replication defective adenovirus comprising a deletion in the E1A, E1B and E3 regions and further comprising a DNA segment encoding a specific protein of interest operatively linked to a promoter and (b) a pharmaceutically acceptable carrier for said vector. Examples of proteins of interest would include, but not be necessarily limited to, CFTR and  $\alpha$ 1-antitrypsin.

The NIH seeks licensee(s) who, in accordance with requirements and regulations governing the licensing of government-owned inventions (37 CFR 404), has the most meritorious plan for the development of a therapeutic agent(s) to meet the needs of the public and with the best terms for the government. NIH intends to grant the selected licensee(s) a world-wide royalty-bearing license(s) to practice the inventions embodied in U.S. Patent 6,013,638 entitled "Adenovirus Comprising Deletions on the E1A, E1B and E3 Regions for Transfer of Genes to the Lung" U.S. Patent Application S/N 09/364,839 entitled "Adenovirus-Mediated Transfer of Genes to the Lung"; U.S. Patent Application S/N 09/307,141 entitled "Adenovirus-Mediated Transfer of Genes to the Lung" and U.S. Patent Application S/N 08/442,262 entitled "Replication Deficient Recombinant Adenovirus Vector". The United States of America is an assignee for the patent rights in these inventions.

**ADDRESSES:** Licensing information, a copy of the U.S. patent or applications referenced to above or a copy of the NIH License Application may be obtained by contacting Richard U. Rodriguez, M.B.A., at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804 (telephone 301/496-7056 ext 287; fax 301/402-0220; and E-mail rr154z@nih.gov). A signed Confidential Disclosure Agreement is required to receive a copy of any patent application.

**SUPPLEMENTARY INFORMATION:** One of the hurdles to overcome in most forms of somatic gene therapy is the specific delivery of a therapeutic gene, encoding a therapeutic protein, to the organ manifesting the disease. In the case of the lung, a functional gene can be delivered directly to the respiratory epithelium by means of tracheal installation. One serious disadvantage with this approach is encountered with the use of vectors (such as retroviruses) that require proliferation of the target cells for expression of the newly transferred gene because only a small proportion of alveolar and airway

epithelial cells go through the proliferative cycle in one day and because a large proportion of these cells are terminally differentiated. Use of the claimed recombinant adenoviral vector to transfer a gene to the respiratory epithelium *in vivo* circumvents the problem of slow target-cell proliferation. Other advantages would include: rare recombination events; no known associations of human malignancies with adenoviral infections despite common human infection with adenoviruses; the adenovirus genome can be manipulated to accommodate foreign genes expressing proteins ranging in size from small peptides up to a peptide of 7.0 to 7.5 kB in length; and live adenovirus has been safely used as a human vaccine.

Dated: March 24, 2000.

**Jack Spiegel,**

*Director, Division of Technology Development and Transfer, Office of Technology Transfer.*

[FR Doc. 00-8107 Filed 3-31-00; 8:45 am]

**BILLING CODE 4140-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of Meeting**

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of a meeting of the Advisory Committee to the Director, National Cancer Institute.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

*Name of Committee:* Advisory Committee to the Director, National Cancer Institute.

*Date:* April 24, 2000.

*Time:* 11:30 AM to 1:30 PM.

*Agenda:* To discuss the Colorectal Cancer Progress Review Group Report.

*Place:* National Institutes of Health, National Cancer Institute, Building 31, Room 11A03, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Susan J. Waldrop, Executive Secretary, National Institutes of Health, National Cancer Institute, Office of Science Policy, Bethesda, MD 20892, 301/496-1458.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer

Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398; Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: March 24, 2000.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 00-8091 Filed 3-31-00; 8:45 am]

**BILLING CODE 4140-01-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**National Cancer Institute; Notice of Meeting**

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 meeting of the Director's Consumer Liaison Group.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(6) and 552b(c)(9)(B), Title 5 U.S.C., as amended. The discussions could reveal information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy and the premature disclosure of discussions related to personnel and programmatic issues would likely to significantly frustrate the subsequent implementation of recommendations.

*Name of Committee:* Director's Consumer Liaison Group.

*Date:* April 17-18, 2000.

*Open:* April 17, 2000, 8:30 AM to 5:00 PM.

*Agenda:* NCI Director's Report; Status of the NCI Communications Reorganization; Clinical Trial System; Accessibility and appropriateness of NCI services and resources.

*Place:* National Institutes of Health, Natcher Conference Center, Conference Room D, Bethesda, MD 20892.

*Closed:* April 18, 2000, 8:30 AM to 4:00 PM.

*Agenda:* To discuss confidential administrative and personnel issues related to membership and functioning of the DCLG.

*Place:* National Institutes of Health, Natcher Conference Center, Conference Room D, Bethesda, MD 20892.

*Contact Person:* Elaine Lee, Acting Executive Secretary, Office of Liaison