

for the opportunity for public comment on proposed data collection projects, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) of 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: A Survey of Estimated GFR Reporting Practices of Clinical Laboratories: Type of Information Collection Request: New. Need and Use of Information Collection: This study will assess the level of U.S. clinical laboratory reporting of estimated GFR as a measure of kidney function. This will be accomplished through baseline and follow-up surveys of a representative sample of clinical laboratories in the U.S. Information will

be used to establish baseline data necessary to measure an anticipated increased in use of estimated GFR, following the implementation of the NKDEP's communications and Lab Working Group (LWG) activities promoting use of estimated GFR for patients at risk for kidney disease. The LWG, whose members are experts in their field, strongly believes that routine reporting of estimated GFR will result in a significant increase in early detection of chronic kidney disease, therefore enabling treatment that can slow or prevent patients' progression to kidney failure. *Frequency of Response:* Baseline survey only. *Affected Public:* Clinical laboratory community. *Type of Respondents:* Laboratory directors. The annual reporting burden is as follow: *Estimated Number of Respondents:*

Anticipate 4,126 completed surveys; *Estimated Number of Responses per Respondent:* Respondents will complete one paper-and-pencil or online survey; *Average Burden Hours Per Response:* .083 hours [5 minutes]; and *Estimated Total Annual Burden Hours Requested:* 342.46 hours. The annualized total cost to respondents is estimated at \$11,759.10. (**Note:** Completing this survey is similar to other data reporting carried out by lab directors. Since lab directors will be able to responded to the survey within their usual workday, this collection of information will not cost labs.employers additional time and money.) There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

| Type of respondents | Estimated number of respondents | Estimated number of responses per respondent | Average burden hours per response | Annual total burden hours requested |
|-------------------------------------|---------------------------------|--|-----------------------------------|-------------------------------------|
| Clinical Laboratory Directors | 4,126 | 1.0 | .083 | 342.46 |
| Total | 4,126 | 1.0 | .083 | 342.46 |

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 responded, 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 Elisa Gladstone, MPH, Project Officer, Associate Director, National Kidney Disease Education Program, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Building 31, Center Dr., Room 9A06, Bethesda, MD 20892, or call non-toll free number (301) 435-8116 or e-mail your request, including your address to, gladstonee@niddk.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: January 17, 2006.

Elisa H. Gladstone,

MPH, Project Officer, Associate Director, National Kidney Disease Education Program, National Institute of Diabetes and Digestive and Kidney Diseases, 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.

Intraperitoneal Injection of Pseudovirions Carrying a Toxin Leads to Significantly Reduced Tumor Size

Michael M. Gottesman et al. (NCI) U.S. Provisional Application filed 01 Dec 2005 (HHS Reference No. E-163-2005/0-US-01)

Licensing Contact: Michelle A. Booden; 301/451-7337; boodenm@mail.nih.gov

SV40-based pseudovirions show great promise in the cancer gene therapy field. SV40 vectors very efficiently deliver genes such as anti-viral agents, DNA vaccine, genes for chemoprotection, suicide genes, and antiangiogenic genes. The immediate application for this technology is to target plasmid DNA to cancerous cells as a gene therapy treatment for various human carcinomas. In previous studies, NCI investigators Chava Kimchi-Sarfaty and Michael Gottesman have

demonstrated that SV40 infectious particles delivering DNA encoding a toxin to tumors can be used as a novel cancer treatment.

This invention discloses a method for delivering a toxin such as *Pseudomonas* exotoxin (PE38) to tumor cells. Administration of the SV40 infectious particle can be by parenteral administration, which includes intraperitoneal, intravenous, intramuscular, subcutaneous, intraorbital, intracapsular, intraspinal, or intrasternal. This disclosure also provides a combined method of use of SV40 infectious particle/PE38 with a chemotherapeutic agent, such as doxorubicin. Interestingly, this combination is very effective at reducing tumor size while eliminating many of the side effects of conventional chemotherapy. This delivery system has a commercial advantage as a new method to increase efficacy and reduce side effects of standard chemotherapies.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Transcytosis of Adeno-Associated Viruses

John A. Chiorini and Giovanni Di Pasquale (NIDCR)
PCT Application No. PCT/US2005/03183 filed 08 Sep 2005 (HHS Reference No. E-298-2004/0-PCT-02)

Licensing Contact: Jesse Kindra; 301/435-5559; kindraj@mail.nih.gov.

The invention relates to a method for delivering nucleic acids to a variety of cells including those of the gut, kidney, lung and central nervous system. The underlying cells of such organs are covered by a barrier of endothelial or epithelial cells which can limit the transfer of nucleic acids, or other potentially therapeutic agents, to the underlying target cells. To overcome this limitation, the method employs certain members of the parvovirus family to transcytose the barrier cells. During transcytosis, the virus passes through these barrier cells and can infect cells of the underlying layer. Therefore, this method could facilitate the transfer of nucleic acids to cells that currently available viral vectors are unable to reach.

The method could be applied to the treatment of neurodegenerative diseases such as Parkinson's, Alzheimer's, Huntington's, lysosomal storage diseases, the dominant spinal cerebellar ataxias, and Krabbe's disease without the need for stereotactic injection. The method could potentially also be used

in the treatment of genetic muscle disorders such as muscular dystrophy. Several of the viruses described in the invention are serologically distinct and could be used in patients who have developed an immune response to other vectors. This work is part of an ongoing effort to develop AAV vectors for gene transfer. Other key technology related to this invention, such as several vector platforms, production, purification methods, and target cell tropism is available for licensing.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Treatment of Hyperproliferative Epithelial Skin Diseases by Topical Application of Hydroxylated Aromatic Protein Cross-Linking Compounds

Caroline Stanwell et al. (NCI)

U.S. Patent No. 5,610,185 issued 11 Mar 1997 (HHS Reference No. E-067-1995/0-US-01)

Licensing Contact: George Pipia; 301/435-5560; pipia@mail.nih.gov

In recent years there has been a dramatic increase in the incidence of skin disease. Increase in exposure to UV light has contributed to the increase in premalignant skin lesions such as actinic keratoses. In the U.S. over 700,000 individuals suffer from superficial squamous and basal cell carcinoma. In addition, other skin diseases such as plantar and genital warts are extremely common. Currently, the treatment for these types of skin diseases include surgical resection or freezing the tissue to destroy the desired cells. Topical treatments, for example acidic compounds or cytotoxic agents, are also employed. However, none of the above treatments are without drawbacks. Surgical methods may be painful and the current topical treatments are not selective for hyperproliferative cells, not always curative, and may be toxic. This invention embodies a series of compounds, hydroxylated aromatic protein cross-linking agents, that can be applied topically and are useful for premalignant and malignant superficial neoplasias of the skin and for the treatment of basal and squamous cell carcinomas.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Pharmaceutical Compositions and Methods for Preventing Skin Tumor Formation and Causing Regression of Existing Tumors

Stuart R. Yuspa et al. (NCI)
U.S. Patent Application No. 10/445,251 filed 27 May 2003, claiming priority to 29 Mar 1991 (HHS Reference No. E-014-1991/0-US-08)

Licensing Contact: George Pipia; 301/435-5560; pipia@mail.nih.gov.

Toxic drugs used to treat epithelial cancers often kill both normal and tumorous cells whereas retinoids used to prevent tumor formation appear to have a suppressive rather than a curative effect. The compositions and methods of administration described in this invention are based on indole carbazole, which causes terminal differentiation of tumor cells by exploiting a normal physiologic pathway. They can be used to regress as well as prevent skin tumors.

In addition to licensing, the technology is available for further development through collaborative research opportunities with the inventors.

Dated: January 17, 2006.

Steven M. Ferguson,

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

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