

children with moderate to severe asthma for a tailored Asthma Counselor case management intervention program and for an in depth examination of the genetic and environmental risk factors associated with asthma. We expect that about 6,000 parents or guardians will have to be interviewed in order to identify 1,000 eligible cases.

Case management will be designed to address the unique challenges presented to these children with asthma in post-Katrina New Orleans and will draw upon the prior Inner City Asthma intervention programs of the National Institutes of Health. It will also include the best components of the locally based Step Together New Orleans (Steps) and the Open Airways (American Lung Association) programs, among others. Each child will undergo a baseline assessment in the form of a questionnaire administered to their parents or guardians. This will contain questions concerning their demographics, stress, access to care, medication use, current and past symptoms, quality of life, knowledge and attitudes about asthma, and environmental exposures. The questionnaire will be administered by professional interviewers and will take about 1 hour to complete. Each child will also undergo a baseline clinical assessment for pulmonary function,

allergen skin prick testing for indoor and outdoor allergens including molds, and blood draws for allergen specific IgE and genetic studies. Following the baseline assessments, the Asthma Counselors will refer the children to selected clinics for treatment and will monitor their progress by conducting periodic follow-up assessments which include a phone call with standardized questions about morbidity, treatment and exposures every two months (about 15 min each) and 2 periodic evaluations of pulmonary function. A final assessment will occur at the end of the year similar to the baseline assessment and take about 1 hour to complete.

In light of the impact of environmental exposures on asthma, a complete evaluation will also be conducted of each child's housing. This will entail the collection of environmental samples such as settled dust samples for potential allergens and triggers for asthma exacerbation (dust mite, cockroach, cat, dog, mouse, and endotoxin) and air for airborne fungal spores. The houses will be evaluated by trained technicians for the presence of mold, mildew, evidence of smoking, water leaks, disrepair, pests and other potential asthma triggers. The ultimate goal of this study is to develop case management and environmental intervention strategies for this

population of post-Katrina children to reduce their asthma morbidity and improve their quality of life. These strategies could potentially be used to intervene in other future disasters similar to hurricane Katrina.

Estimated Number of Respondents: The estimated number of respondents is 40,000 which includes the parents or guardians of 1,000 children enrolled in the case management intervention and environmental assessment programs.

Affected Public: Individuals or households.

Type of Respondents: Children with asthma 5 to 12 years of age or their parents or guardians.

The annual reporting burden is as follows:

Estimated Number of Responses per Respondent: The table below shows the estimated number of responses per respondent per activity over the next two years.

Average Burden Hours per Response: 0.36; and

Estimated Total Annual Burden Hours Requested: 20,500 over 2 years.

The average annual burden hours requested is 10,250. The annualized cost to respondents is estimated at \$7.20 (assuming \$20 hourly wage). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

Activity	Estimated number of respondents	Estimated responses per respondent	Average burden hours per response	Estimated total burden hours requested
School-based eligibility screening	40,000	1	0.25	10,000
Enrollment interview	6,000	1	0.5	3,000
Baseline QX assessment	1,000	1	1.25	1,250
Baseline Medical assessment	1,000	1	2	2,000
Phone follow-up	1,000	6	0.25	1,500
Pulmonary function assessment	1,000	2	1	2,000
Yearly follow-up	1,000	1	2	1,000
Total				20,750

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: Patricia Chulada, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541-7736 or e-mail your request, including your address to chulada@niehs.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: May 4, 2006.

Richard A. Freed,
Associate Director for Management, NIEHS.
[FR Doc. 06-4571 Filed 5-15-06; 8:45am]
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.

T-Cell Receptor Recognizing Renal Cell Carcinoma

Description of Invention: Renal cell carcinoma (RCC) is the most common renal tumor with approximately 30,000 cases per year in the USA. The survival rate for this cancer is very low, where only 10% of patients survive because this carcinoma is resistant to most chemotherapies.

This technology describes a T-cell receptor that was cloned from a human immune cell. This T-cell receptor recognizes a number of human kidney tumors and is not limited to use in patients with specific MHC types. This cell was able to kill other kidney cancer cells in other patients, and when this T-cell was introduced into other human immune cells, these cells also acquired the ability to kill kidney cancer cells. This invention also describes novel methods using dendritic cells to generate both CD4+ and CD8+ RCC-reactive T-cells for use in antigen identification and therapeutic protocols. This is the first and only cloned T-cell receptor that recognizes a majority of human kidney tumors.

Applications: A therapeutic for patients suffering from renal cell carcinoma; a novel method using dendritic cells to prime T-cell responses; a novel method of constructing and inserting light chain genes of the T-cell receptor into other patient's T-cells.

Market: There are approximately 30,000 new estimated cases of renal cell carcinoma per year in the USA. The total market size in the USA in the range of \$2 billion dollars.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Qiong J. Wang, Ken-ichi Hanada and James C. Yang (NCI).

Publication: QJ Wang et al., "Generating renal cancer-reactive T-cells using dendritic cells (DCs) to present autologous tumor," *J Immunother.* 2005 Nov-Dec 28(6):551-559.

Patent Status: U.S. Provisional Application No. 60/776,194 filed 24 Feb 2006 (HHS Reference No. E-106-2006/0-US-01).

Licensing Status: Available for non-exclusive or exclusive licensing.

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

Collaborative Research Opportunity: The NCI Surgery Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize T-cell receptors and their clinical use as cancer treatments. Please contact Dr. Steven Rosenberg at (301) 496-4164 or sar@mail.nih.gov for more information.

Preparation of a Peptide Targeted Human RNase, RGD-Eosinophil Derived Neurotoxin (RGD-EDN) To Specifically Target Tumor Vasculature

Description of Technology: Cancer is the second leading cause of death in the United States and it is estimated that there will be approximately 600,000 deaths caused by cancer in 2006. A major drawback of the existing chemotherapies is the cytotoxic side-effects that are associated with them. Thus, there is a need to develop new therapeutic approaches with reduced side-effects.

Anti-angiogenic therapy is a recent approach in cancer therapeutics targeting the formation of blood vessels that are necessary for tumor growth. Anti-angiogenic therapeutic agents are generally devoid of toxic side-effects, recently gaining attention as cancer therapeutics with tremendous promise. Recently, the anti-angiogenic molecule bevacizumab (Avastin), a monoclonal antibody against the vascular endothelial growth factor (VEGF), has gained approval from the FDA for the first-line treatment of metastatic colon cancer in combination with standard chemotherapy.

This technology describes a novel anti-angiogenic method for treating cancer. The $\alpha\beta 3$ -integrin is upregulated on tumor endothelial cells and can bind RGD (Arg-Gly-Asp) peptides. By tagging the RGD peptide with the normally non-cytotoxic eosinophil-derived neurotoxin

(EDN), this RNase molecule can be targeted to human vascular endothelial cells where it becomes cytotoxic. These RGD-EDN molecules inhibit the adhesion of HUVEC cells in response to endothelial growth factors. These molecules have also been shown to inhibit tumor growth in mice with Kaposi's sarcoma. This technology has therapeutic potential for a broad spectrum of cancer related diseases alone, or in combination with existing therapies.

Applications: A novel therapeutic molecule, RGD tagged EDN (RGD-EDN); an anti-angiogenic cancer therapy for targeting RGD-EDN to endothelial cells via binding to the RGD receptor $\alpha\beta 3$ integrin.

Market: 600,000 deaths from cancer related diseases estimated in 2006; the technology platform involving novel anti-angiogenic cancer therapy technology has a potential market of more than 2 billion U.S. dollars.

Development Status: The technology is currently in the pre-clinical stage of development.

Inventors: Dianne L. Newton, Zhongyu Zhu, and Susanna M. Rybak (NCI).

Publications:

1. A Dricu et al., "A synthetic peptide derived from the human eosinophil-derived neurotoxin induces apoptosis in Kaposi's sarcoma cells," *Anticancer Res.* 2004 May-Jun; 24(3a):1427-1432.

2. M Fani et al., "Comparative evaluation of linear and cyclic 99mTc-RGD peptides for targeting of integrins in tumor angiogenesis," *Anticancer Res.* 2006 Jan-Feb; 26(1A):431-434.

3. DL Newton et al., "Construction and characterization of RNase-based targeted therapeutics," *Methods Mol Biol.* 2003; 207:283-304.

4. A Capello et al., "Anticancer activity of targeted proapoptotic peptides," *J Nucl Med.* 2006 Jan; 47(1):122-129.

Patent Status: U.S. Provisional Application No. 60/782,968 filed 15 Mar 2006 (HHS Reference No. E-094-2006/0-US-01).

Licensing Status: Available for non-exclusive and exclusive licensing.

Licensing Contact: David Lambertson, Ph.D.; 301/435-4632; lambertsond@od.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute, Biological Testing Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Peptide Targeted Human RNases. Please contact Bjarne Gabrielsen at (301) 846-5465 or bjg@nih.gov for more information.

Adoptive Immunotherapy With Autologous Natural Killer Cells

Description of Technology: Dr. Rosenberg and colleagues have clearly demonstrated that T-lymphocytes can mediate the regression of metastatic melanoma. However, not all patients with cancer are eligible for or respond to this type of immunotherapy. In some patients, the tumor infiltrating lymphocytes (TIL) do not expand sufficiently, or do not exhibit sufficient tumor specific reactivity.

Studies in mice have shown that adoptive transfer of NK cells activated *in vitro* can significantly reduce the load of Acute Myelogenous Leukemia (AML), and intravenously-injected autologous NK cells have been shown to significantly decrease melanoma tumor outgrowths. To this end, Dr. Rosenberg and colleagues have developed an alternative type of immunotherapy, which involves the adoptive transfer of autologous natural killer (NK) cells. This method consists of three parts: (a) Isolation and expansion of NK cells *ex vivo*; (b) Administration of nonmyeloablative lymphodepleting chemotherapy regimen to the patient; and (c) Reconstitution of the patient's immune system by infusion of NK cells and interleukin 2. This approach also offers the possibility of treating AIDS, immunodeficiency, and autoimmune diseases for which immune cells can impact the clinical outcome.

Development Status: This work has not yet been published; however, Dr. Rosenberg and colleagues have developed a clinical protocol and are awaiting IRB approval to begin enrolling patients in a Phase I clinical trial.

Inventors: Steven A. Rosenberg and Maria R. Parkhurst (NCI).

Publications:

1. IRB approved protocol in press.
2. SA Rosenberg and ME Dudley, "Cancer regression in patients with metastatic melanoma after the transfer of autologous antitumor lymphocytes," *Proc. Natl. Acad. Sci USA* 2004 Oct 5;101 Suppl 2:14639-14645.
3. ME Dudley et al., "Adoptive cell transfer therapy following non-myeloablative but lymphodepleting chemotherapy for the treatment of patients with refractory metastatic melanoma," *J. Clin. Oncol.* 2005 Apr 1;23(10):2346-2357.
4. U Siegler et al., "Activated natural killer cells from patients with acute myeloid leukemia are cytotoxic against autologous leukemic blasts in NOD/SCID mice," *Leukemia* 2005 Dec;19(12):2215-2222.
5. F Lozupone et al., "Effect of human natural killer and gammadelta T cells on

the growth of human autologous melanoma xenografts in SCID mice," *Cancer Res.* 2004 Jan 1;64:378-385.

Patent Status: U.S. Provisional Application No. 60/779,863 filed 06 Mar 2006 (HHS Reference No. E-090-2006/0-US-01).

Licensing Status: Available for non-exclusive or exclusive licensing.

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

Collaborative Research Opportunity: The NCI Surgery Branch is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Natural Killer (NK) cells for their clinical use as cancer treatments. Please contact Dr. Steven Rosenberg at (301) 496-4164 or sar@mail.nih.gov for more information.

Sensitive Antibody-Based Assay for the Measurement of c-Met Concentration Shed in Bodily Fluids Useful in the Diagnosis and Prognosis of Cancer

Description of Technology: This invention described and claimed in these patent applications provide for methods and assays which may be used to diagnose and follow the progression of cancers associated with c-Met expression. The data supporting this application suggests that c-Met expression may be an appropriate biomarker in certain types of cancer. In particular, the applications describe a sensitive assay useful for monitoring levels of c-Met shed in the urine or blood. The assay was developed using commercially available reagents. The applications contain data, derived from patient samples, supporting the clinical utility of the assay. In particular, the data shows the use of the assay to detect levels of shed c-Met in patients with bladder cancer, renal cancers and prostate cancer. Data showing the applicability of the assay for glioblastoma was derived using murine models of cancer for glioblastoma. Data showing the applicability of the assay for breast cancer, melanoma and prostate cancer was derived using various human cell line model systems.

HGF/met signaling has been most widely studied in settings related to cancer. It has been demonstrated to have a role in metastasis and angiogenesis. In addition to cancer, HGF activity has also been linked, through its role in apoptosis, to Alzheimer's disease and cardiovascular disease.

These applications have not been published. The investigators presented their work in a poster session at the AACR Meeting April 16-20, 2005 (Abstract 2788) (<http://www.abstrackonline.com/viewer/viewAbstract.asp?CKey=%7bAD0F2047-14FA-4BEE-AE98-0DAF2F26EF1A%7d&MKey=%7b218FF7E7-9F17-4030-9BB4-8C029B0C9B4E%7d&AKey=%7b728BCE9C-121B-46B9-A8EE-DC51FDFC6C15%7d&SKey=%7bA5AFD1D5-1D83-4F0E-9FD5-AC7119D62D8E%7d>).

At this time there are no other publications related to this work. Dr. Bottaro's Web site is <http://ccr.cancer.gov/Staff/Staff.asp?profileid=8410>.

Inventors: Donald Bottaro and Pathirage G. Dharmawardana (both of NCI).

Patent Status: U.S. Provisional Application No. 60/734,993 filed 08 Nov 2005 (HHS Reference No. E-261-2005/0-US-01) and U.S. Provisional Application No. 60/780,626 filed 09 Mar 2006 (HHS Reference No. E-261-2005/1-US-01), entitled "Methods for Diagnosing and Monitoring the Progression of Cancer." At this time only U.S. Patent protection has been sought for this technology. There are no foreign counterpart patent applications.

Licensing Status: Available for non-exclusive or exclusive licensing.

Licensing Contact: Susan S. Rucker, Esq.; 301/435-4478; ruckersu@mail.nih.gov.

Collaborative Research Opportunity: The National Cancer Institute, Urologic Oncology Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize HGF/c-Met signaling as it relates to tissue repair and regeneration, cancer, and other diseases. Please contact Brian W. Bailey, Ph.D. at (301) 451-2158 or bbailey@mail.nih.gov for more information.

Use of Cripto-1 as a Biomarker for Neurodegenerative Disease and Method of Inhibiting Progression Thereof

Description of Technology: Cripto-1 is a gene that is currently thought to play an important role in several cancers, and is being developed in clinical trials as a cancer therapeutic. Presented in this invention is another use of Cripto-1 as a biomarker and possible therapeutic target for a variety of neurodegenerative diseases, including NeuroAIDS, Alzheimer's disease (AD), multiple sclerosis (MS), amyotrophic lateral sclerosis (ALS), Parkinson's disease (PD) and encephalitis. Cripto-1 and concomitant protein expression appears to be overexpressed by 20-fold or more in the brains of macaque monkeys and humans afflicted with NeuroAIDS. This expression is confined to neurons related to neurodegeneration.

Inhibition of Cripto-1 may be associated with inhibiting the progression of these diseases via a disclosed method for inhibiting the expression or downstream signaling pathways mediated by Cripto-1. This inhibition can be achieved through the expression of various inhibitory oligonucleotides. Additionally, the development of antibodies against Cripto-1 has already been achieved for the detection of Cripto-1 in human pathological specimens.

It is estimated that by 2050, 14 million Americans will suffer from AD, representing national annual costs for caring and due to productivity lost of approximately \$160 billion. Despite active research in this area, there remains urgent need to identify differentially expressed genes in and to develop methods for detecting neurodegenerative disease through assaying expression levels of specific genes. Currently, there are no drugs directed at inhibiting Cripto-1 as a therapeutic agent for AD or other neurodegenerative diseases. This invention holds the promise of market opportunities through pursuing development of Cripto-1 as a biomarker for diagnosis of and possible target for therapeutic intervention of these diseases.

Inventors: David S. Salomon (NCI) et al.

Publications:

1. CL Parish et al., "Cripto as a target for improving embryonic stem cell-based therapy in Parkinson's disease," *Stem Cells* 2005 Apr; 23(4):471-476.

2. HB Adkins et al., "Antibody blockade of the Cripto CFC domain suppresses tumor cell growth *in vivo*," *J Clin Invest.* 2003 Aug 15; 112(4): 575-587.

Patent Status: U.S. Provisional Application No. 60/508,750 filed 03 Oct 2003 (HHS Reference No. E-075-2003/0-US-01); PCT Application No. PCT/US04/32649 filed 01 Oct 2004 (HHS Reference No. E-075-2003/0-PCT-02), which published as WO 2005/033341 on 02 Jun 2005.

Licensing Status: Available for non-exclusive or exclusive licensing.

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

Collaborative Research Opportunity: The National Cancer Institute, Mammary Biology and Tumorigenesis Laboratory, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact Jeffrey Hildesheim, Ph.D. at (301) 435-1569 or

hildesheimj@mail.nih.gov for more information.

Dated: May 5, 2006.

David R. Sadowski,

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

[FR Doc. E6-7428 Filed 5-15-06; 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(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the meeting of the National Cancer Advisory Board.

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.

A portion of the meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4), and 552b(c)(6), 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 Cancer Advisory Board.

Open: June 14, 2006, 8 a.m. to 4:30 p.m.

Agenda: Program reports and presentations; Business of the Board.

Place: National Cancer Institute, 9000 Rockville Pike, Building 31, C Wing, 6th Floor, Conference Room 10, Bethesda, MD 20892.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327. (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Closed: June 14, 2006, 4:30 p.m. to Adjournment.

Agenda: Review of grant applications.

Contact Person: Dr. Paulette S. Gray, Executive Secretary, National Cancer Institute, National Institutes of Health, 6116 Executive Boulevard, 8th Floor, Room 8001, Bethesda, MD 20892-8327. (301) 496-5147.

Name of Committee: National Cancer Advisory Board.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: deainfo.nci.nih.gov/advisory/ncab.htm, where an agenda and any additional information for the meeting will be posted when available.

(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: May 9, 2006.

Anna Snouffer,

Acting Director, Office of Federal Advisory Committee Policy.

[FR Doc. 06-4561 Filed 5-15-06; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed 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 following meeting.

The meeting 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 Cancer Institute Special Emphasis Panel; CA-07-001, CA-07-007 (STTR), CA-07-006 (SBIR) Innovation Technologies for the Molecular Analysis of Cancer.

Date: June 15-16, 2006.

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

Agenda: To review and evaluate grant applications.

Place: Marriott Gaithersburg Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.