DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request: The National Survey of Physicians Attitudes Regarding the Care of Cancer Survivors (SPARCCS) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute (NCI), the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection was previously published in the **Federal Register** on July 31, 2008 (Vol. 73, No. 148, p. 44751) and allowed 60-days for public comment. There were no public comments received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institutes of Health may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Proposed Collection: Title: NIH–Survey of Physicians Attitudes Regarding the Care of Cancer Survivors (SPARCCS). *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The purpose of this study is to identify the beliefs, knowledge, attitudes, and practices of primary care physicians and cancer specialists regarding the components described by the IOM. These data will inform the process of standardization of survivorship care practices; augment the data collected in other cancer survivorship studies and monitor the progress being made toward achieving NCI strategic goals of improving the quality of cancer care across the cancer control continuum. This questionnaire adheres to The Public Health Service Act, Section 412 (42 U.S.C. 285a–1) and Section 413 (42 U.S.C. 285a–2), which authorizes the Division of Cancer Control and Population Sciences of the National Cancer Institute (NCI) to establish and support programs for the detection, diagnosis, prevention and treatment of cancer; and to collect, identify, analyze and disseminate information on cancer research, diagnosis, prevention and treatment. *Frequency of Response:* Once. *Affected Public:* Individuals and Businesses. *Type of Respondents:* Primary care and medical oncology physicians practicing in a non-federal facility. The annual reporting burden is estimated at 904 hours as shown in Table 1. The total burden hours is estimated at 1808 hours over the two year field period of the study. There is no capital, operating or maintenance costs to report.

TABLE 1—ESTIMATES OF ANNUAL BURDEN HOURS

Type of respondents	Survey	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Receptionists	Screener	2,033	1	5/60	169
Family Practice	PCP Instrument	250	1	20/60	83
General Internists	PCP Instrument	250	1	20/60	83
OB/GYNs	PCP Instrument	50	1	20/60	17
Oncologists	Oncology Instrument	550	1	20/60	183
Receptionists & Administrators	Follow-Up Phone Calls.	1,103	4	5/60	368
Total		4,236			904

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.

Direct Comments To OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the Attention: NIH Desk Officer, Office of Management and Budget, at *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Arnie Potosky, Ph.D., Task Order Monitor, Applied Research Branch, Division of Cancer Control and Population Sciences, National Cancer Institute, National Institutes of Health, Bethesda, Maryland, 20892–7344, or call non-toll-free number (301)402–3362 or e-mail your request, including your address to: *potoskya@mail.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

Dated: August 23, 2008.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison Office, National Institutes of Health.

[FR Doc. E8–23443 Filed 10–2–08; 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.

Matriptase Hypomorphic Mouse Model of a Human Ichthyosis

Description of Technology: Available for licensing are mice with greatly reduced levels of matriptase, a membrane protease involved in epithelial development, immune function, and carcinogenesis. These mice were created to study autosomal recessive ichthyosis with hypotricosis (ARIH), an inherited human disease that has been linked to a mutation in the ST14 gene that encodes matriptase. These mice manifest the same defects seen in people afflicted by ARIH, so it can be an effective model for studying the role of matriptase in disorders that affect skin development.

Applications:

• Research tool for skin development research.

• Model to develop and test therapeutics for treating skin disorders, including skin cancer.

• Model immunity and allergy.

Advantages: Well characterized animal model closely related to a human genetic disorder.

Market: Ichthyosis is a series of genetic skin diseases characterized by dry, thickened, scaling skin that affects more than one million Americans. Presently, there is no cure for ichthyosis, only treatments to help manage symptoms.

Development Status: Well characterized mouse model of human ARIH.

Inventors: Thomas H. Bugge (NIDCR) *et al.*

Publication: K List et al. Autosomal ichthyosis with hypotrichosis syndrome displays low matriptase proteolytic activity and is phenocopied in ST14 hypomorphic mice. J Biol Chem. 2007 Dec 14;282(50):36714–36723.

Patent Status: HHS Reference No. E–323–2008/0—Biological Material. Patent protection is not being pursued for this technology.

Licensing Status: Available for non-exclusive licensing under a Biological Materials License Agreement.

Licensing Contact: Adaku Nwachukwu, J.D.; 301–435–5560; *madua@mail.nih.gov.*

Collaborative Research Opportunity: The National Institute of Dental and Craniofacial Research, Oral and Pharyngeal Cancer Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact David W. Bradley, Ph.D. at 301–402–0540 or *bradleyda@nidcr.nih.gov* for more information.

Prostatic Adenocarcinoma Cells Expressing or Lacking the Tumor Suppressor Gene PTEN

Description of Technology: PTEN is a tumor suppressor gene that is frequently deleted or mutated in a variety of human cancers, including prostate, breast, endometrial, lung, and ovarian cancers. In prostate cancer cells, PTEN deletion is the most common event observed. The loss of PTEN is thought to play and important role in tumor cell proliferation and metastasis due to a lack of control of the signaling pathways that mediate cellular processes such as apoptosis and migration. Previously PTEN had been shown to downregulate cyclin D1 expression as well as regulate p53 protein levels and transcriptional activity, and recently the inventors of this technology have shown that PTEN decreases surface IGF–IR protein levels in prostate cancer cell lines in an Akt-independent manner.

PC3 cells are prostate cancer cells that lack PTEN gene. This technology describes PC3 cells that overexpress the PTEN gene. These cell lines can be used to study the role of the PTEN gene in cancer growth and metastasis.

Market:

• Prostate cancer is the most common type of cancer found in American men, and it has been estimated that there were more than 230,000 new cases in the U.S. in 2007. Prostate cancer is also the second leading cause of cancer death in men.

• In the U.S. over 2 million women have been treated for breast cancer, with more than 200,000 women diagnosed in the year 2007 alone. Breast cancer is the second leading cause of cancer death in women.

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

Inventors: Derek LeRoith and Michael Quon (NIDDK).

Publication: H Zhao et al. PTEN inhibits cell proliferation and induces apoptosis by downregulating cell surface IGF–IR expression in prostate cancer cells. Oncogene 2004 Jan 22;23(3):786–794.

Patent Status: HHS Reference No. E–292–2008/0—Research Tool. Patent protection is not being pursued for this technology.

Licensing Status: Available for licensing.

Licensing Contact: Whitney A. Hastings; 301–451–7337; *hastingw@mail.nih.gov*.

Fully Human Anti-Human NKG2D Monoclonal Antibody

Description of Technology: Available for licensing is a fully human monoclonal antibody (KYK–2.0 IgG1) with high specificity and affinity to human NKG2D, a stimulatory or costimulatory receptor located on the cell surface of natural killer (NK) cells and CD8+ T cells. NKG2D plays a role in mediating immune responses in autoimmune and infectious diseases and cancer and it makes NKG2D an attractive target for therapeutic intervention. Nonetheless, monoclonal antibodies to NKG2D that are suitable for clinical investigations have not been available. In solution, KYK–2.0 IgG1 interferes with the cytolytic activity of human NK cells. When immobilized, KYK–2.0 IgG1 induces human NK cell activation. The dual antagonistic and agonistic activity promises a broad range of therapeutic applications.

Application: Therapeutic fully human monoclonal antibody for a variety of indications including autoimmune and infectious diseases, cancer, and transplantation.

Advantage: The dual antagonistic and agonistic activity in concert with low immunogenicity suggests broad and potent therapeutic utility of KYK–2.0 IgG1 and its derivatives.

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

Market:

• Monoclonal antibody market is one of the fastest growing and most lucrative sectors of the pharmaceutical industry with a 48.1% growth between 2003 and 2004.

• Monoclonal antibody market is estimated to be worth $30.3 billion in 2010.

Inventors: Christoph Rader and Ka Yin Kwong (NCI)

Related Publication: KY Kwong, S Baskar, H Zhang, CL Mackall, C Rader. Generation, affinity maturation, and characterization of a human anti-human NKG2D monoclonal antibody with dual antagonistic and agonistic activity. J Mol

Biol., in press (available online 2008 Sep 16, *doi:10.1016/j.jmb.2008.09.008*).

Patent Status: U.S. Provisional Application No. 61/086,027 filed 04 Aug 2008 (HHS Reference No. E–211–2008/0–US–01).

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

Licensing Contact: Jennifer Wong; 301–435–4633; *wongje@mail.nih.gov*.

Collaborative Research Opportunity: The Experimental Transplantation and Immunology Branch, Center for Cancer Research, National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the fully human anti-human NKG2D monoclonal antibody KYK–2.0 IgG1. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Methods for the Detection and Treatment of Lung Cancer

Description of Technology: Lung cancer is the third most common malignant disease and the first leading cause of cancer death in the western world. Non-small cell lung cancer (NSCLC) is one of the leading causes of death accounting for nearly 30% of all cancer deaths. Despite considerable research, lung cancer remains difficult to diagnose and treat effectively. Current chemotherapeutic regimens provide poor survival benefits and the unmet clinical need among lung cancer patients is very high. The prognosis is very bleak since most patients are diagnosed with lung cancer at a late stage.

The inventors have discovered that approximately 20% of common adult NSCLC have an aberrant activation of CRTC gene members with marked induction of CRTC regulated genes. CRTC activation is linked with the loss of LKB1/STK11 kinases which results in CRTC underphosphorylation and enhanced nuclear localization. As the LKB1/STK11 signaling pathways has been exploited in potential cancer therapeutic treatments, this novel unrecognized consequence the loss of LKB1/STK11 function associated with aberrant CRTC activation in cancer offers new candidate diagnostic and therapeutic targets for NSCLC.

Applications:

• Novel cancer diagnostics and therapeutic treatments.

• Method to detect and treat lung cancer.

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

Market:

• Lung cancer is the leading cause of cancer deaths among both men and women in the U.S.

• The NSCLC market was estimated to be worth US$3.7 billion in 2006 and will increase by 17% by 2012.

Inventors: Frederic Kaye and Amy Coxon (NCI).

Patent Status: U.S. Provisional Application No.61/036,830 filed 13 Mar 2008 (HHS Reference No. E–069–2008/0–US–01).

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

Licensing Contact: Jennifer Wong; 301–435–4633; wongje@mail.nih.gov.

Human Perilipin Proteins

Description of Technology: Perilipins are important regulators of lipid storage in fat cells. These proteins stabilize fat droplets and control their breakdown by controlling access of lipid-degrading enzymes. Since these proteins are central to the storage and breakdown of body fat it very likely that they are crucial for the regulation of body weight. Perilipin expression is elevated in obese animals and humans. Mutations in the perilipin gene are associated with increased risk of obesity in women. Importantly, when the perilipin gene is inactivated the obesity of model mice is reversed. Therefore, perilipin could be a good candidate for therapeutic targeting to treat obesity in humans.

This NIH invention claims DNA sequences of splice variants that code for human perilipin protein isoforms and methods of expressing the recombinant protein in bacteria or mammalian cells. It also claims substantially purified perilipin proteins and methods for detecting their presence in a biological sample.

Applications:

• Drug development for obesity.

• Diagnostics for detection of perilipins.

• Antigens for antibody production.

• Markers for identifying true adipocytes.

Advantages:

• Cloned DNA sequences ready for protein expression.

• Isoforms allow greater flexibility in designing therapeutics.

Development Status: Pre-clinical.

Inventors: Constantine Londos, Andrew S. Greenberg, Alan R. Kimmel, John J. Egan (NIDDK).

Related Publication: AS Greenberg et al. Perilipin, a major hormonally regulated adipocyte-specific phosphoprotein associated with the periphery of lipid storage droplets. J Biol Chem. 1991 Jun 15;266(17):11341–11346.

Patent Status:

• U.S. Patent No. 6,074,842 issued 13 Jun 2000 (HHS Reference No. E–111–1991/0–US–03).

• U.S. Patent No. 5,585,462 issued 17 Dec 1996 (HHS Reference No. E–111–1991/1–US–01).

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

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

Dated: September 29, 2008.

Richard U. Rodriguez,

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

[FR Doc. E8–23436 Filed 10–2–08; 8:45 am]

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Murine Monoclonal Antibodies Effective To Treat Respiratory Syncytial Virus

Description of Technology: Available for licensing through a Biological Materials License Agreement are the murine MAbs described in Beeler et al, ''Neutralization epitopes of the F glycoprotein of respiratory syncytial virus: effect of mutation upon fusion function,'' J Virol. 1989 Jul;63(7):2941–