these requirements, a standard Investigational Drug Accountability Report Form (NIH 2564) was designed to account for drug inventories and usage by protocols. The data obtained from the drug accountability record will be used to keep track of the dispensing of investigational anticancer agents to patients. It is used by NCI management to ensure that investigational drug supplies are not diverted for inappropriate protocol or patient use. The information is also compared to patient flow sheets (protocol reporting forms) during site visits conducted for each investigator once every three years. All comparisons are done with the intention of ensuring protocol, patient and drug compliance for patient and drug compliance for patient safety and protections.

Frequency of Response: Daily.

Affected Public: State or local governments, businesses or other for-profit. Federal agencies or employees, non-profit institutions, and small business or organizations.

Type of Respondents: Investigators, pharmacist, nurses, pharmacy technicians, data manager. The annual reporting burden is divided into two major areas. These are the audits of Drug Accountability Forms by Government and its contractors and the use of the forms by clinical research sites. The burden is as follows:

Federal Burden: 1,700 audits are conducted of clinical research sites, a minimum of three Drug Accountability Forms are reviewed at the audit. Each form requires a ½ hour to review.

Number of Respondents: 1,700.

Number of Responses per Respondent: 3.

Average Burden per Response: 0.5 hours.

Annual Burden Hours: 2,250 hours.

Clinical Trial Site Burden: The annualized respondents' burden for recordkeeping is estimated to require 6,240 hours. The recordkeeping burden represents an average time required for multiple entries (4 minutes or 0.1 hour per entry) on the drug accountability form, the average number of forms maintained by each recordkeeper and the number of recordkeepers.

Drug Accountability Forms

Number of Record Keepers: 3,990.

Number of Responses per Respondent: 16.

Average Burden per Response: 0.1.

Annual Burden Hours: 6,240 hours.

There are no Capital Costs, Operating Costs, and Maintenance Cost to report.

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 Charles L. Hall, Jr., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, Division of the Cancer Treatment and Diagnosis, and Centers, National Cancer Institute, Executive Plaza North, Room 7148, 9000 Rockville Pike, Bethesda, MD 20892 or call non-toll-free number 301–496–5725 or e-mail your request, including your address to: *Hallch@mail.nih.gov.*

Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days following the date of this publication.

Dated: August 3, 2007.

Ann E. Duane,

Acting NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E7–15750 Filed 8–10–07; 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.

An Improved Chromosomal Comparative Genomic Hybridization (CGH) Microarray for the Detection of Cancer Associated Genome Amplification and Deletion Events

Description of Technology: The progression and therapeutic response of cancer is closely associated with chromosomal instability (i.e. genomic amplifications and deletions). The most widely used technique to detect these small changes in the genome is CGH. CGH utilizes nucleic acid hybridization to oligonucleotide features corresponding to specific, predetermined regions of the genome to detect DNA copy number changes. Due to the size of the human genome, it is necessary to have high-density features to detect small amplification and deletion events within the genome.

The current invention is based on a CGH microarray with oligonucleotide features that provides a high-density coverage. More specifically, the inventors have used 60-mer oligonucleotide features within a previously shown set of 36 tumor associated genes/genomic regions and have successfully detected small changes in DNA copy number with high density coverage (1 feature per 400bp). Furthermore, the inventors have used a fade-out design for coverage of the flanking regions and cover the remainder of the genome at an average density of 1 feature per 100kb.

Applications:

1. CGH microarray can be used to detect small regions of genomic instability within cancer associated genes, while larger events can also be detected with similar efficacy.

2. Gene amplification and deletion profiles of patient samples can be used in diagnosis and therapeutic decision making.

Advantages:

1. Easy to use, CGH microarray technique, based on current technology.

2. Technology detects small changes in tumor associated genomic instability

more efficiently than current available technologies.

3. The average coverage of Agilent oligoarray is 1 per 35kb of human genome, while the average coverage of the currently described technology is 1 per 400bp.

Developmental Status: The technology is ready for use.

Benefits: More than 600,000 cancer deaths are estimated to occur in 2007. Efficient diagnosis and informed decision making will aid in improved clinical management of cancer. This technology can rapidly diagnose cancer and thus help in proper clinical management leading to improved overall survival and quality of life of patients suffering from cancer. The current in-vitro diagnostics market is valued at $30 billion dollars and expected to grow.

Inventors: Xiaolin Wu, David Munroe, Ester Rozenblum, Hongling Liao (NCI/SAIC).

Patent Status: U.S. Provisional Application No. 60/911,411 filed 12 April 2007 (HHS Reference No. E–122–2007/0–US–01).

Licensing Contact: Thomas P. Clouse, J.D.; 301/435–4076; *clouset@mail.nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute Laboratory of Molecular Technology is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize CGH microarrays. Please contact John D. Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Methods and Compositions for Treating Diseases and Disorders Associated with Natural Killer T–Cells

Description of Technology: The invention relates to the discovery that C12 beta-D-galactosyl ceramide may be used to deplete or inactivate NKT cell populations. These findings suggest methods for using C12 beta-D-galactosyl ceramide to treat conditions that would benefit from depletion of NKT cells, such as certain autoimmune diseases (e.g. lupus, MS) and AIDS.

The presence of NKT cells can be associated with either beneficial effects or pathology. Deficiencies in NKT cells are associated with at least some types of autoimmune disease, including type 1 diabetes and autoimmune gastritis in mice. In contrast, NKT cells augment autoantibody secretion and lupus development in lupus-prone mouse models and therefore lupus patients may benefit from the depletion of NKT cells. The remission state of multiple sclerosis (MS) is also associated with decreased levels of NKT cells, suggesting NKT cell depletion as a method of treatment for MS.

Inventors: John R. Ortaldo and Robert H. Wiltrout (NCI).

Patent Status:

U.S. Provisional Application No. 60/488,339 filed 17 July 2003 (HHS Reference No. E–282–2002/0–US–01).

PCT Application No. PCT/US2004/22913 filed 16 Jul 2004, which published as WO 2005/014008 on 17 Feb 2005 (HHS Reference No. E–282–2002/0–PCT–02).

European Application No. 04778424.4 filed 16 Jul 2004, which published as 1653977 on 10 May 2006 (HHS Reference No. E–282–2002/0–EP–03).

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

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

P53 and VGEF Regulate Tumor Growth of NO2 Expressing Cancer Cells

Description of Technology: The increased expression of nitric oxide synthase 2 (NOS2), an inducible enzyme that produces nitric oxide (NO), has been found in a variety of human cancers. It also has been shown that NOS2-specific inhibitors can reduce the growth of experimental tumors in mice. These findings suggest a pathophysiological role for NO in the development and progression of cancer. However, the function of NO and NOS2 in carcinogenesis is uncertain. NO had been found to either inhibit or stimulate tumor growth, and high concentrations of NO also are known to induce cell death in many cell types including tumor cells. On the other hand, the lower concentrations of NO that are found in human tissue can have an opposite effect and protect against programmed cell death, or apoptosis, from various stimuli. The role of NO and NOS2 in tumor progression, particularly with respect to p53, therefore need to be further defined.

This invention comprises methods of screening for modulators of NOS2 expression in p53 mutant cells, both *in vivo* and *in vitro*, as well as methods for predicting the chemotherapeutic benefit of administering NOS2-inhibitors to cancer patients. It has been demonstrated that NOS2-expressing cancer cells with wild-type p53 have reduced tumor growth in athymic nude mice whereas NOS2-expressing cancer cells with mutated p53 have accelerated tumor growth. Therefore, this invention has potential application for a number of cancers that overexpress NOS2 and have a high frequency of p53 mutations, including breast, brain, head, neck, lung and colon cancers.

Applications:

1. Method to treat cancer with NOS2 inhibitors.

2. Method to screen for NOS2 modulators.

3. Method to predict therapeutic benefits of NOS2 inhibitors in patients.

Market:

1. An estimated 1,444,920 new cancer diagnoses in the U.S. in 2007.

2. 600,000 deaths caused by cancer in the U.S. in 2006.

3. Cancer is the second leading cause of death in United States.

4. It is estimated that market for cancer drugs would double to $50 billion a year in 2010 from $25 billion in 2006.

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

Inventors: Stefan Ambs and Curt Harris (NCI).

Publications:

1. JE Goodman *et al.* Nitric oxide and p53 in cancer-prone chronic inflammation and oxyradical overload diseases. Environ Mol Mutagen. 2004;44(1):3–9.

2. LJ Hofseth *et al.* Nitric oxide in cancer and chemoprevention. Free Radic Biol Med. 2003Apr 15;34(8):955–968.

Patent Status:

U.S. Patent Application No. 11/195,006 filed 01 Aug 2005 (HHS Reference No. E–223–1998/0–US–04).

U.S. Patent Application No. 09/830,977 filed 02 May 2001 (HHS Reference No. E–223–1998/0–US–03).

PCT Patent Application No. PCT/US1999/27410 filed 17 Nov 1998 (HHS Reference No. E–223–1998/0–PCT–02).

U.S. Provisional Patent Application No. 60/109,563 filed 23 Nov 1998 (HHS Reference No. E–223–1998/0–US–01).

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

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

Dated: August 3, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–15749 Filed 8–10–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Clinical Center; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as