care providers and self reports. The ultimate objective is to compare the health care utilization of insured and uninsured PLCO participants. The PLCO data provides a unique opportunity to study health care seeking behavior after an abnormal cancer screening test and the effect of lack of health insurance. Individuals randomized to the intervention arm of the trial received screening for the PLCO cancers. Individuals with positive findings were referred to their doctors for follow-up care, but no additional care was provided by the trial. The PLCO study then collected detailed information on tests received for diagnosis, clinical presentation of disease, and cancer treatment. Since the PLCO original data collection had not recorded the health insurance of participants at the time of their screening, it is necessary to collect it retrospectively. This feasibility study will request information from 50 physicians and 150 participants. The aims are to determine:

(1) The total number of physicians to be contacted to obtain insurance information on all PLCO participants who had a positive cancer screening test;

(2) The percentage of physicians willing and able to provide insurance information;

(3) The percentage of respondents' patients with and without insurance, and possibly distribution of patients by insurance type;

(4) The number of participants for whom the insurance status can be only determined by self report;

(5) The percentage of PLCO participants who are willing to respond to the survey;

(6) The percentage of individuals who are willing to provide information on insurance status and type; and,

(7) The potential proportion of PLCO participants without health insurance at the time of screening.

The results of this feasibility study will be used to design of a larger study to examine the health care behavior of insured and uninsured PLPCO participants. This is relevant to understand the results of the PLCO Cancer Screening Trial and other screening trials currently being conducted in the U.S. The success of these trials is conditional on participants' access to care following a recommendation for follow-up. Uninsured individuals may be more likely to join these trials than insured ones in order to get free preventive care. They may also be more likely to not seek, or delay seeking, care after an abnormal screening test even though they are encouraged to get care and they may be highly motivated to receive the best care possible. It is relevant for other decision makers to understand whether uninsured persons are receiving appropriate care after abnormal screening results. The efforts to control cancer disease and the loss of life associated with it are concentrated on population wide screening. These endeavors may be compromised if a significant proportion of the population does not get appropriate follow-up after screening or does not get the care known to be effective for their disease.

Frequency of Response: One time. *Affected Public:* Individuals or households; Businesses or other for-profit. *Type of Respondents:* Men and women older than 55 who participated in the PLCO Screening trial and physicians who provided care for them. The annual reporting burden is shown in the following table.

Type of respondents	Number of respondents	Frequency of response	Average burden hours per response	Annual hour burden
PLCO participants	150	1	5 minutes (0.08)	12.5
Physicians office staff	50	1	20 minutes (0.33)	16.7
Totals	200			29.2

The annualized cost to respondents is estimated at: $488. There are no Capital Costs to report. There are no Operating or Maintenance Costs 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 Dr. Maria Pisu, Division of Preventive Medicine, University of Alabama at Birmingham, MT 628, 1530 3rd Avenue South, Birmingham, AL 35294–4410, or call non-toll-free number (205) 975–7366 or e-mail your request, including your address to: *mpisu@uab.edu.*

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: December 11, 2007.

Vivian Horovitch-Kelley,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. E7–24872 Filed 12–20–07; 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.

A Clinically Proven Therapeutic Treatment and Diagnostic Tool for Mesothelin Expressing Cancers: A Novel Recombinant Immunotoxin SS1P (anti-mesothelin dsFv–PE38)

Description of Technology: Mesothelin is a cell surface glycoprotein, whose expression is largely restricted to mesothelial cells in normal tissues. Mesothelin has been shown to be highly expressed in many cancers including malignant mesothelioma, ovarian cancer, lung cancer, pancreatic carcinomas, gastric carcinomas, and other cancers. Mesothelin has been shown to be a target for immunotherapy and is also being used as a tumor marker.

The technology relates to the SS1P immunotoxin that can be used to kill cells expressing mesothelin on their surface, such as mesothelioma, ovarian cancer, lung cancer, pancreatic cancer and stomach cancer. Additionally, it can be used for the detection of mesothelin expressing cells present in a biological sample.

The SSIP protein is an immunotoxin generated by the fusion of an anti-mesothelin antibody Fv fragment with a particularly high affinity (SS1), and a ~38 kDa portion of *Pseudomonas Exotoxin* A (PE38).

Applications: SS1P can be used as a therapy for mesothelin expressing cancers. The immunotoxin can be used as a standalone treatment and in combination with standard chemotherapy.

Advantage: SS1P immunotoxin is available for use and has been successfully tested clinically for the treatment of several mesothelin expressing cancers, such as mesothelioma and ovarian cancer with low side effects.

Development Status: Phase 1 studies have been completed for mesothelin expressing cancers such as mesothelioma and ovarian cancer. Phase 2 studies to begin shortly for combination therapy using SS1P and standard chemotherapy.

In addition to an active Investigational New Drug (IND) application, there are two associated orphan drug designations with this agent.

Inventors: Ira Pastan (NCI) *et al.*

Relevant Publications:

1. R Hassan *et al.* Phase I study of SS1P, a recombinant anti-mesothelin immunotoxin given as a bolus I.V. infusion to patients with mesothelin-expressing mesothelioma, ovarian, and pancreatic cancers. Clin Cancer Res. 2007 Sep 1;13 (17):5144–5149.

2. Y Zhang *et al.* Synergistic antitumor activity of taxol and immunotoxin SS1P in tumor-bearing mice. Clin Cancer Res. 2006 Aug 1;12(15):4695–4701.

Patent Status: U.S. Patent No. *7,081,518* issued 25 Jul 2006, entitled ''Anti-Mesothelin Antibodies Having High Binding Affinity'' (HHS Reference No. E–139–1999/0–US–07)

Related Intellectual Property:

1. U.S. Patent No. 4,892,827 entitled ''Recombinant Pseudomonas Exotoxin: Construction of an Active Immunotoxin with Low Side Effects'' [HHS Ref. No. E–385–1986/0];

2. U.S. Patent Nos. 6,051,405, 5,863,745, and 5,696,237 ''Recombinant Antibody-Toxin Fusion Protein'' [HHS Ref. No. E–135–1989/0];

3. U.S. Patents 5,747,654, 6,147,203, and 6,558,672 entitled ''Recombinant Disulfide-Stabilized Polypeptide Fragments Having Binding Specificity'' [HHS Ref. No. E–163–1993/0];

4. U.S. Patent No. 6,153,430, and U.S. Patent Application No. 09/684,599 ''Nucleic Acid Encoding Mesothelin, a Differentiation Antigen Present on Mesothelium, Mesotheliomas and Ovarian Cancers'' [HHS Ref. No. E–002–1996/0];

5. U.S. Patent 6,083,502 entitled ''Mesothelium Antigen and Methods and Kits for Targeting It'' [HHS Ref. No. E–002–1996/1];

6. U.S. Patent Application 09/581,345: ''Antibodies, Including Fv Molecules, and Immunoconjugates Having High Binding Affinity for Mesothelin and Methods for Their Use'' [HHS Ref. No. E–021–1998/0];

7. PCT Application No. PCT/US01/18503, ''Pegylation of Linkers Improves Antitumor Activity and Reduces Toxicity of Immunoconjugates'' [HHS Ref. No. E–216–2000/2];

8. PCT Application No. PCT/US2006/018502 and U.S. Patent Application No. 60/681,104, entitled ''Anti-Mesothelin Antibodies Useful For Immunological Assays'' [HHS Ref. No. E–015–2005/0–US–01]; and

9. And any related foreign filed national stage applications claiming priority to such patent applications and patents listed above.

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

Licensing Contact: David A. Lambertson, Ph.D.; 301/435–4632; *lambertsond@mail.nih.gov.*

cDNA Encoding a Gene BOG and Its Protein Product

Description of Invention: Available for licensing is BOG (B5t Over-Expressed Gene) with the gene product pRb of the well-known tumor suppressor gene RB, retinoblastoma susceptibility gene. The complex formed between Rb and BOG typically does not contain E2F–1 *in vivo.* This binding property suggests that cells which are transformed/transfected with cDNA or other functional nucleotide sequences which encode the BOG gene product will be useful as tools for studying cell cycle control and oncogenesis.

Studies using rat liver epithelial cell (RLE) lines which are resistant to the growth inhibitory effects of TGF-beta1 and primary liver tumors have been shown to over-express BOG. Moreover, when normal RLE continuously over-express BOG the cells become transformed and the transformed cells are able to form hepatoblastoma-like tumors when transplanted into nude mice. Therefore, biologics derived from BOG may be useful as diagnostics or therapeutics.

Applications: Method to diagnose and treat liver cancer; Method to study cell cycle control and oncogenesis; Liver cancer therapeutics.

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

Market: Liver cancer is the third leading cause of cancer death worldwide, and the fifth most common cancer in the world; Post-operative five year survival rate of HCC patients is 30–40%.

Inventors: Snorri S. Thorgeirsson *et al.* (NCI).

Relevant Publication: JT Woitach *et al.* A retinoblastoma-binding protein that affects cell-cycle control and confers transforming ability. Nat Genet. 1998 Aug;19(4):371–374.

Patent Status: U.S. Patent No. 6,727,079 issued 27 Apr 2004 (HHS Reference No. E–009–1998/2–US–02).

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

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

Collaborative Research Opportunity: The National Cancer Institute (NCI), Center for Cancer Research, Laboratory of Experimental Carcinogenesis, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize BOG (B5t Over-Expressed Gene) with the gene product pRb. Please contact John Hewes, Ph.D. at the NCI Technology Transfer Center at

hewesj@mail.nih.gov or (301) 496–0477 for more information.

Dated: December 14, 2007.

Steven M. Ferguson,

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

[FR Doc. E7–24784 Filed 12–20–07; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: Emergency Response Grants Regulations—42 CFR part 51—(OMB No. 0930–0229)—Extension

This rule implements section 501(m) of the Public Health Service Act (42 U.S.C 290aa), which authorizes the Secretary to make noncompetitive grants, contracts or cooperative agreements to public entities to enable such entities to address emergency substance abuse or mental health needs in local communities. The rule establishes criteria for determining that a substance abuse or mental health emergency exists, the minimum content for an application, and reporting requirements for recipients of such funding. SAMHSA will use the information in the applications to make a determination that the requisite need exists; that the mental health and/or substance abuse needs are a direct result of the precipitating event; that no other local, state, tribal or Federal funding sources available to address the need; that there is an adequate plan of services; that the applicant has appropriate organizational capability; and, that the budget provides sufficient justification and is consistent with the documentation of need and the plan of services. Eligible applicants may apply to the Secretary for either of two types of substance abuse and mental health emergency response grants: Immediate awards and Intermediate awards. The former are designed to be funded up to $50,000, or such greater amount as determined by the Secretary on a case-by-case basis, and are to be used over the initial 90-day period commencing as soon as possible after the precipitating event; the latter awards require more documentation, including a needs assessment, other data and related budgetary detail. The Intermediate awards have no predefined budget limit. Typically, Intermediate awards would be used to meet systemic mental health and/or substance abuse needs during the recovery period following the Immediate award period. Such awards may be used for up to one year, with a possible second year supplement based on submission of additional required information and data. This program is an approved user of the PHS–5161 application form, approved by OMB under control number 0920–0428. The quarterly financial status reports in 51d.10(a)(2) and (b)(2) are as permitted by 45 CFR 92.41(b); the final program report, financial status report and final voucher in 51d.10(a)(3) and in 51d.10(b)(3–4) are in accordance with 45 CFR 92.50(b). Information collection requirements of 45 CFR part 92 are approved by OMB under control number 0990–0169. The following table presents annual burden estimates for the information collection requirements of this regulation.

42 CFR citation	Number of respondents	Responses per respondent	Hours per response	Annual burden hours
Immediate award application:				
51d.4(a) and 51d.6(a)(2)	3	1	3	*9
51d.4(b) and 51d.6(a)(2) Immediate Awards	3	1	10	*30
51d.10(a)(1)—Immediate awards—mid-program report if applicable	3	1	2	*6
Final report content for both types of awards:				
51d.10(c)	6	1	3	18
Total	6			18

*This burden is carried under OMB No. 0920–0428.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, One Choke Cherry Road, Rockville, MD 20857 *AND* e-mail her a copy at *summer.king@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Dated: December 13, 2007.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. E7–24824 Filed 12–20–07; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

Oral Declarations No Longer Satisfactory as Evidence of Citizenship and Identity

AGENCIES: U.S. Customs and Border Protection, Department of Homeland Security.