

Regulation citation	Number of respondents	Frequency of responses	Hours per response (minutes)	Total burden hours
60.11(a)(7) Requests by Researchers for Aggregated Data .....	100	1	30	50
60.14(b) Practitioner Places a Report in Disputed Status .....	666	1	5	55
60.14(b) Practitioner Statement .....	2,563	1	45	1,922
60.14(b) Practitioner Requests for Secretarial Review .....	117	1	480	936
60.3 Entity Registration—Initial .....	500	1	60	500
60.3 Entity Registration—Update .....	643	1	5	54
60.11(a) Authorized Agent Designation—Initial .....	500	1	15	125
60.11(a) Authorized Agent—Update .....	86	1	5	7
60.12(c) Account Discrepancy Report .....	300	1	15	75
60.12(c) Electronic Funds Transfer Authorization .....	363	1	15	91
60.3 Entity Reactivation .....	100	1	60	100
<b>Total</b> .....				<b>293,644</b>

Numbers in the table may not add up exactly due to rounding.

Send comments to Susan Queen, PhD, HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received within 60 days of this notice.

Dated: February 22, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

[FR Doc. E7–3446 Filed 2–27–07; 8:45 am]

**BILLING CODE 4165–15–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Advisory Commission on Childhood Vaccines; Notice of Meeting**

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

*Name:* Advisory Commission on Childhood Vaccines (ACCV).

*Date and Time:* March 7, 2007, 1 p.m.–5 p.m., EST. March 8, 2007, 9 a.m.–3:30 p.m., EST.

*Place:* Audio Conference Call and Parklawn Building, Conference Rooms G & H, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Wednesday, March 7, from 1 p.m. to 5 p.m., and on Thursday, March 8, from 9 a.m. to 3:30 p.m. The public can join the meeting in person at the address listed above or by audio conference call by dialing 1–888–947–9967 on March 7 and 8 and providing the following information:

*Leader's Name:* Dr. Geoffrey Evans.

*Password:* ACCV.

*Agenda:* The agenda items for the March meeting will include, but are not limited to: A discussion of VICP outreach activities; an overview of the Vaccine Adverse Event Reporting System, including the requirements for the reporting of adverse events; a report from the ACCV Futures Workgroup; and updates from the Division of

Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics and Evaluation Research (Food and Drug Administration). Agenda items are subject to change as priorities dictate.

*Public Comments:* Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation, to: Ms. Cheryl Lee, Principal Staff Liaison, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857 or e-mail: [clee@hrsa.gov](mailto:clee@hrsa.gov). Requests should contain the name, address, telephone number, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter by mail or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the comment period. These persons will be allocated time as it permits.

*For Further Information Contact:* Anyone requiring information regarding the ACCV should contact Ms. Cheryl Lee, Principal Staff Liaison, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–2124 or e-mail: [clee@hrsa.gov](mailto:clee@hrsa.gov).

*Notification:* Due to inclement weather, the requirement that the public be notified of this meeting at least 15 calendar days in advance was not met.

Dated: February 22, 2007.

**Alexandra Huttinger,**

*Acting Director, Division of Policy Review and Coordination.*

[FR Doc. E7–3559 Filed 2–27–07; 8:45 am]

**BILLING CODE 4165–15–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Submission for OMB Review; Comment Request; Request for Genetic Studies in a Cohort of U.S. Radiologic Technologists**

**SUMMARY:** Under the provisions of section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Cancer Institute, 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 December 29, 2006, pages 78445–78446 and allowed 60 days for public comment. No public comments were 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:* Genetic Studies in a Cohort of U.S. Radiologic Technologists (formerly known as “Generic Clearance to Collect Medical Outcome and Risk Factor Data from a Cohort of U.S. Radiologic Technologists”). *Type of Information Collection Request:* Renewal with change of a previously approved collection (OMB No. 0925–0405, expiration 02/28/2007). *Need and Use of Information Collection:* The primary aim of this collection is to substantially increase knowledge about the possible modifying role of genetic variation on the long-term health effects associated with protracted low-to moderate-dose

radiation exposures. With this submission, the NIH, Office of Communications and Public Liaison, seeks to obtain OMB's approval to collect biospecimens and risk factor data in this ongoing cohort study of U.S. radiologic technologists to assess genetic and molecular risk factors for cancer, and to evaluate possible modifying effects of genetic variation on radiation-cancer relationships. Researchers at the National Cancer Institute and The University of Minnesota have followed a nationwide cohort of 146,000 radiologic technologists since 1982, of whom 110,000 completed at least one of three prior questionnaire surveys and 18,400 are deceased. This cohort is unique because estimates of cumulative radiation dose to specific organs (e.g. breast) are available and the cohort is largely female, offering a rare opportunity to study effects of low-dose radiation exposure on breast and thyroid cancers, the two most sensitive organ sites for radiation carcinogenesis in women. Overall study objectives are: (1) To quantify radiation dose-response for cancers of the breast, thyroid, and other radiogenic sites, and selected benign conditions related to cancer (e.g. thyroid nodules); (2) to assess cancer risk associated with genotypic, phenotypic, or other biologically measurable factors (e.g. serum levels of C-reactive protein, insulin growth factors or binding proteins); and (3) to determine if genetic variation modifies the radiation-related cancer risk. A third follow-up of this cohort was completed during the past three years. During

2003–2005, the “Third Survey” questionnaire was mailed or administered by telephone to 101,694 living cohort members who had completed at least one prior survey; 73,838 technologists (73% response) completed the survey. The questionnaire elicited information on: Medical outcomes to assess radiation-related risks; detailed employment data to refine the occupational radiation dose estimates; and behavioral and residential histories for estimating lifetime ultraviolet (UV) radiation exposure. Analyses of these data are currently underway and findings will address an important gap in the scientific understanding of radiation dose-rate effects, i.e., whether cumulative exposures of the same magnitude have the same health effects when received in a single or a few doses over a very short period of time (as in the atomic bomb or therapeutic exposures) or in many small doses over a protracted period of time (as in medical or nuclear occupational settings).

There are few, if any, other study populations in which both quantified breast radiation doses and blood samples are available for individuals with protracted low-dose radiation exposures. The current petition is for renewal with change of the previous clearance to administer a Genetic Studies Questionnaire and collect biospecimens from 10,000 cohort members who completed at least one prior survey. These individuals would serve as a comparison group for case-cohort studies of gene main effects and

gene-radiation interactions. To improve statistical power to detect such associations, we plan to select the comparison sample based on dose; this is to ensure inclusion of sufficient numbers of high-dose individuals. The Genetic Studies Questionnaire will collect information on: Family history of cancer; reproductive history in women (e.g. pregnancy outcomes, menopause); personal medical radiation exposures (e.g. diagnostic x-rays, therapeutic irradiation); and personal history of chemotherapy. The survey will be in optical-read format for computerized data capture. A blood collection kit will be mailed to technologists along with the Genetic Studies Questionnaire; they will be asked to take the kit to a phlebotomist to have a single tube of blood drawn and returned to the study laboratory by pre-paid Federal Express overnight delivery. Ongoing efforts to medically validate self-reported cancers and other medical outcomes will continue. The annual reporting burden is as follows: *Frequency of Response:* On occasion. *Affected Public:* U.S. radiologic technologists who willingly participated in earlier investigations to quantify the carcinogenic risks of protracted low-to moderate-dose occupational radiation exposures. *Estimated Number of Respondents:* 4,233. *Estimated Number of Responses per Respondent:* 1. *Average Burden Hours per Response:* 1.3. *Annual Burden Hours Requested:* 5,630. Total cost to respondents is estimated at \$157,471. There are no capital costs, operating costs and/or maintenance costs to report.

RESPONDENT AND BURDEN ESTIMATE—OMB NO. 0925–0405

Type of respondent	Number of respondents (3 yr)	Frequency of response	Total respondents (3 yr)	Average hours per response	Total hours (3 yr)	Annual hour burden
<b>Genetic Studies/Risk Factor Survey and Blood Collection</b>						
Sub-Cohort .....	10,000	1	10,000	1.66666	16,666	5,555
<b>Medical Validation</b>						
Hospitals/ Physicians .....	2,700	1	2,700	0.08333	225	75
Total: .....	12,700	.....	12,700	.....	16,891	5,630

*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 functioning of the National Cancer Institute, 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: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Michele M. Doody, Radiation Epidemiology Branch, National Cancer Institute, Executive Plaza South, Room 7040, Bethesda, MD 20892-7238, or call non-toll-free at 301-594-7203 or e-mail your request, including your address to: [doodym@mail.nih.gov](mailto:doodym@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: February 16, 2007.

**Rachelle Ragland-Greene,**

*NCI Project Clearance Liaison, National Institutes of Health.*

[FR Doc. E7-3435 Filed 2-27-07; 8:45 am]

**BILLING CODE 4104-01-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.

#### Methods of Determining the Prognosis of Hepatocellular Carcinoma

**Description of Technology:** Hepatocellular carcinoma (HCC) represents an extremely poor prognostic cancer that remains one of the most common and aggressive malignancies worldwide. A major hallmark of HCC is intrahepatic metastasis and post-surgical reoccurrence. With current diagnostic methods, HCC patients are often diagnosed with end-stage cancer and have poor survival. Thus, there is a need for an accurate method to identify HCC and its proclivity for metastases/relapse, particularly at early stages of this disease.

The inventors have discovered a unique set of microRNA (miRNA) biomarkers that are associated with HCC metastasis/recurrence. This miRNA signature was validated in an independent cohort of 110 HCC samples as an independent predictor of HCC prognosis and likelihood of metastasis and relapse. In particular, the inventors provide evidence that these miRNA markers can predict HCC metastasis in the early stages of cancer. This methodology may enable clinicians to effectively stratify patients for appropriate cancer treatment and prioritize liver transplantation candidates.

**Applications:** (1) Method to prognose HCC, patient survival and likelihood of HCC metastasis/relapse; (2) Diagnostic tool to aid clinicians in determining appropriate cancer treatment; (3) Compositions that inhibit miRNA HCC biomarkers such as siRNA; (4) Method to treatment HCC patients with inhibitory miRNA compositions.

**Market:** (1) Primary liver cancer accounts for about 2% of cancers in the U.S., but up to half of all cancers in some undeveloped countries; (2) Post-operative five year survival rate of HCC patients is 30-40%.

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

**Inventors:** *Xin Wei Wang et al.* (NCI).

**Publication:** *Budhu et al.* A Unique Metastasis-related MicroRNA Expression Signature Predicts Survival and Recurrence in Hepatocellular Carcinoma, manuscript in preparation.

**Patent Status:** U.S. Provisional Application No. 60/884,052 filed 09 Jan 2007 (HHS Reference No. E-050-2007/0-US-01).

**Licensing Availability:** Available for exclusive or non-exclusive licensing.

**Licensing Contact:** Jennifer Wong; 301/435-4633; [wongje@mail.nih.gov](mailto:wongje@mail.nih.gov).

#### A Varicella-Zoster Virus Mutant that is Markedly Impaired for Latent Infection Available for the Development of Shingles Vaccines and Diagnostics

**Description of Technology:** Reactivation of latent Varicella-Zoster virus (VZV) infection is the cause of shingles, which is prominent in adults over the age of 60 and individuals who have compromised immune systems, due to HIV infection, cancer treatment and/or transplant. Shingles is a worldwide health concern that affects approximately 600,000 Americans each year. The incidence of shingles is also high in Europe, South America, and India; the latter having an estimated two million individuals affected, yearly. Recent research studies show that VZV vaccines have a significant effect on decreasing the incidence of shingles in elderly.

The current technology describes compositions, cells and methods related to the production and use of a mutant VZV and the development of vaccines against the infectious agent. Latent VZV expresses a limited repertoire of viral genes including the following six open reading frames (ORFs): 4, 21, 29, 62, 63, and 66. The present invention describes an ORF29 mutant VZV that demonstrates a weakened ability to establish latency in animal studies. The current technology provides methods for using the mutant in the development of live vaccines and diagnostic tools. A related invention is described in PCT/US05/021788 (publication number WO2006012092).

**Applications:** Development of vaccines and diagnostics for prevention of shingles.

**Development Status:** Pre-clinical studies have been performed to demonstrate the reduced latency of the ORF29 mutant VZV in animals.

**Inventors:** Jeffrey Cohen (NIAID) and Lesley Pesnicak (NIAID).

**Patent Status:** U.S. Provisional Application No. 60/857,766 filed 09 Nov 2006 (HHS Reference No. E-029-2007/0-US-01).

**Licensing Availability:** Available for licensing and commercial development.

**Licensing Contact:** Chekesha Clingman, Ph.D.; 301/435-5018; [clingmac@mail.nih.gov](mailto:clingmac@mail.nih.gov).

**Collaborative Research Opportunity:** The NIAID Laboratory of Clinical Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize vaccine strains of VZV vaccine with impaired latency. Please contact Kelly Murphy, J.D., M.S., at 301/451-3523 or [murphykt@niaid.nih.gov](mailto:murphykt@niaid.nih.gov) for more information.