County. Family functioning, substance use, sexual behaviors, behavior problems, and community values will inform HIV intervention programs in the community.

This study will address some of the goals of CDC's "CDC HIV Prevention Strategic Plan: Extended Through 2010". CDC plans to meet specific goals by increasing the number of behavior prevention interventions proven effective for Hispanic adolescents, and, increasing the number of Hispanic adolescents who consistently engage in behaviors that reduce risk for acquiring HIV. Additionally, the study data will provide important information that will aid in developing and improving HIV prevention interventions for Hispanic adolescents and their families.

Questionnaires will take from approximately 45 min. (caregivers) to 60 minutes (adolescents) to complete.

There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of respondents and questionnaire	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Hispanic Adolescent				
.				
Screening	400	1	3/60	20
ACASI—Baseline	240	1	1	240
ACASI—4-month follow-up	228	1	1	228
ACASI—12-month follow-up	217	1	1	217
Primary Caregiver of Hispanic Adolescent				
Screening	400	1	3/60	20
ACASI—Baseline	240	1	45/60	180
ACASI—4-month follow-up	228	1	45/60	171
ACASI—12-month follow-up	217	1	45/60	163
TOTAL				1239

Dated: January 22, 2010.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–10–09BR]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC), Agency for Toxic Substances and Disease Registry (ATSDR) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639–5960 or send an e-mail to *omb@cdc.gov.* Send written comments to ATSDR Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Registration of Individuals with Amyotrophic Lateral Sclerosis (ALS) in the National ALS Registry—New—Agency for Toxic Substances and Disease Registry (ATSDR).

Background and Brief Description

On October 10, 2008, President Bush signed S. 1382: ALS Registry Act which amended the Public Health Service Act to provide for the establishment of an Amyotrophic Lateral Sclerosis (ALS) Registry. The activities described are part of the effort to create the National ALS Registry. The purpose of the registry is to: (1) Better describe the incidence and prevalence of ALS in the United States; (2) examine appropriate factors, such as environmental and occupational, that might be associated with the disease; (3) better outline key demographic factors (such as age, race or ethnicity, gender, and family history of individuals who are diagnosed with the disease) associated with the disease; and (4) better examine the connection between ALS and other motor neuron disorders that can be confused with ALS, misdiagnosed as ALS, and in some cases progress to ALS. The registry will collect personal health information that may provide a basis for further scientific studies of potential risks for developing ALS.

During a workshop held by The Agency for Toxic Substances and Disease Registry (ATSDR) in March 2006 to discuss surveillance of selected autoimmune and neurological diseases, it was decided to develop a proposal to build on work that had already been done and coordinate existing datasets to create a larger database, rather than to start from scratch with medical records review and physician reporting. Four pilot projects were funded to evaluate the accuracy and reliability of existing data from the Center for Medicare and Medicaid Services (CMS) and various datasets from the Veterans Administration. Preliminary results indicate that additional ways to identify cases of ALS will be necessary to increase completeness of the registry. Therefore, ATSDR developed a Web site where individuals will also have the opportunity to provide additional information on such things as occupation, military service, and family history of ALS, which is not available in existing records.

The registration portion of the data collection will be limited to information that can be used to identify an individual to assure that there are not duplicate records for an individual. Avoiding duplication of registrants due to obtaining records from multiple sources is imperative to get accurate estimates of incidence and prevalence, as well as accurate information on demographic characteristics of the cases of ALS.

In addition to questions required for registration, there will be a series of short surveys to collect information on such things as military history, occupations, and family history that would not likely be available from other sources.

This project proposes to collect information on individuals with ALS which can be combined with information obtained from existing sources of information. This combined data will become the National ALS Registry and will be used to provide more accurate estimates of the incidence and prevalence of disease as well as the demographic characteristics of the cases. Information obtained from the surveys will be used to better characterize potential risk factors for ALS which will lead to further in-depth studies.

The existence of the Web site will be advertised by ATSDR and advocacy groups such as the Amyotrophic Lateral Sclerosis Association (ALSA) and the Muscular Dystrophy Association (MDA). There are no costs to the respondents other than their time. The estimated annualized burden hours are 2300.

ESTIMATED ANNUALIZED BURDEN HOURS

Forms for ALS respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Validation questions	6,000	1	2/60
Registration of ALS cases	4,667	1	7/60
Cases of ALS completing 1-time surveys	2,334	6	5/60
Cases of ALS completing twice yearly surveys	2,334	2	5/60

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Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention, Agency for Toxic Substances and Disease Registry.

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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.

Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions

Description of Invention: This technology describes a 72 gene model that has been developed for diagnosing less common forms of thyroid cancer like follicular carcinoma and others. The technology detects thyroid cancer using fine needle aspiration (FNA) biopsy and the analysis of differentially expressed thyroid (DET) genes and their encoded proteins. These results provide a molecular classification system for thyroid tumors and this in turn provides a more accurate diagnostic tool for the clinician managing patients with suspicious thyroid lesions. It is related to earlier technology out of the laboratory of Dr. Libutti, US Application No. 11/547,995 entitled "Diagnostic Tool for Diagnosing Benign vs. Malignant Thyroid Lesions" (HHS Reference No. E–124–2004). This latter invention was drawn to a 6 and 10 gene model that distinguishes benign vs. malignant papillary thyroid lesions.

Application: The identification of markers that can determine a specific type of tumor, predict patient outcome or the tumor response to specific therapies.

Advantage: The use of gene profiles to detect thyroid malignancy has the advantage that it complements the current method of diagnosis using FNA, but greatly increases the accuracy of detecting malignant thyroid lesions.

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

Market: It is expected that more than 37,340 new cases of thyroid cancer will be diagnosed in the United States this year. Women will be disproportionately affected constituting 76% of these new cases. Fortunately, this is one of the least deadly cancers; the percentage of people living at least 5 years after being diagnosed is about 97%. However, current methods of diagnosis are inaccurate and many biopsy results are inconclusive and labeled as suspicious or indeterminate because of difficulties in distinguishing benign and malignant thyroid tumors solely on cellular features. Since most nodules usually end up being benign, treatment decisions are greatly impacted because patients with benign nodules may be subjected to unnecessary surgery that will impact their lives considerably. Thus, there is a compelling need to develop more accurate diagnostic tests to detect thyroid cancer.

Inventors: Steven K. Libutti (NCI) *et al.*

Related Publications:

1. Prasad NB, Somervell H, Tufano RP, Dackiw AP, Marohn MR, Califano JA, Wang Y, Westra WH, Clark DP, Umbricht CB, Libutti SK, Zeiger MA. Identification of genes differentially expressed in benign versus malignant thyroid tumors. Clin Cancer Res. 2008 Jun 1;14(11):3327–3337. [PubMed: 18519760]

2. Rosen J, He M, Umbricht C, Alexander HR, Dackiw AP, Zeiger MA, Libutti SK. A six-gene model for differentiating benign from malignant thyroid tumors on the basis of gene expression. Surgery. 2005 Dec;138(6):1050–1056; discussion 1056–1057. [PubMed: 16360390]

3. Mazzanti C, Zeiger MA, Costouros NG, Umbricht C, Westra WH, Smith D, Somervell H, Bevilacqua G, Alexander HR, Libutti SK. Using gene expression profiling to differentiate benign versus malignant thyroid tumors. Cancer Res.