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

Dated: January 22, 2010.

Maryam I. Daneshvar,

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

[FR Doc. 2010–1718 Filed 1–27–10; 8:45 am]

BILLING CODE 4163–18–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.

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.

2004 Apr 15;64(8):2898–2903. [PubMed: 15087409]

Patent Status: PCT Application No. PCT/US2008/10139 entitled "Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions" filed August 27, 2008 (HHS Reference No. E–326–2007/0–PCT–02).

Licensing Status: Available for licensing.

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

Collaborative Research Opportunity: The Center for Cancer Research, Surgery Branch, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize Diagnostic Tool for Diagnosing Benign Versus Malignant Thyroid Lesions. Please contact John D. Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Imaging of Extracellular Proteases in Cells Using Mutant Anthrax Toxin Protective Antigens

Description of Invention: The claimed invention provides highly specific and sensitive methods for in vivo, in vitro, or ex vivo imaging of specific extracellular protease activity using an anthrax binary toxin system. The system targets cells that express extracellular proteases of interest. Such a system would be highly useful since various studies have demonstrated a positive correlation between the activity of extracellular proteases and various diseases and undesirable physiological conditions. For example, breakdown of the extracellular matrix by extracellular proteases is a prerequisite for the invasive growth of malignant cells, metastatic spread of tumors, and other pathological remodeling of tissue. In this case, methods are provided for the imaging of a specific extracellular protease by contacting a cell with: (1) A mutant anthrax toxin protective antigen (mPrAg) that binds to a cell surface receptor of a cell expressing an extracellular protease and is cleaved by a specific extracellular protease expressed by the cell and 2) a ligand that specifically binds to the cleaved mPrAg and is linked to a moiety that is detected by an imaging procedure, thereby forming a ligand-mPrAg complex that is translocated into the cell. The detectable moiety linked to the ligand in the ligand-mPrAg complex can be imaged before, during, or after translocation. Specific disease examples might include, but are not necessarily limited to, cancer, inflammation, and tumor progression or regression.

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

Patent Status: U.S. Patent Application No. 10/488,806 filed 04 Mar 2004 (HHS Reference No. E–295–2001/0–US–03).

Licensing Status: Available for licensing.

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

A Basal Cell Carcinoma Tumor Suppressor Gene

Description of Invention: Novel human nucleic acid sequences and polypeptides derived from the tumor suppressor, PTC or patched gene which have been mapped to human chromosome 9q22.3-q31, have been discovered for use in cancer diagnosis and therapy. Mutations of this gene are associated with Nevoid Basal Cell Carcinoma Syndrome (NBCCS) a disease associated with skin cancer and human developmental defects such as Gorlin Syndrome comprising skeletal defects, craniofacial and brain abnormalities. Methods of detection of PTC in a tissue sample have been found as well as recombinant cells, antibodies, and pharmacological compositions useful in treatment of the disease. Methods of diagnosis of and therapy for NBCCS have also been found. The PTC gene is thought to encode a protein which selectively switches off growth factor production in certain cells by interaction with members of the family of proteins encoded by the "hedgehog" gene, which instructs cells during development and growth. NBCCS is the result of abnormal PTC gene products that encode non-functional or functionally reduced NBCCS polypeptides. This lack of function may be caused by insertions, deletions, point mutations, splicing errors, premature termination codons, missing initiators, etc. The tumors caused by NBCCS are slow growing tumors that rarely metastasize, but which can cause significant morbidity and occasional mortality from local invasion. The PTC gene is also associated with medulloblastomas and trichoepitheliomas.

Newly discovered germline and sporadic mutations associated with NBCCS have been disclosed and claimed in the International (PCT) application.

Inventors: Michael C. Dean (NCI) *et al.*

Patent Status:

- U.S. Patent No. 6,552,181 issued 22 Apr 2003 (HHS Reference No. E–104–1996/1–US–01).
- U.S. Patent No. 7,317,086 issued 08 Jan 2008 (HHS Reference No. E–104–1996/1–US–02).
- Related international patents/patent applications.

Licensing Status: Available for licensing.

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

Dated: January 21, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–1667 Filed 1–27–10; 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.

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Signal-to-Noise Enhancement in Imaging Applications Using a Time-Series of Images

Description of Invention: The invention offered for licensing relates to the field of imaging and specifically to the field of medical imaging. The apparatus and method of the invention provide for noise reduction in imaging applications that use a time-series of images. In one embodiment of the invention, a time-series of images is acquired using a same imaging protocol of the same subject area, but the images are spaced in time by one or more time intervals (*e.g.* 1, 2, 3 * * * seconds apart). A sub-region is projected across