SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL: SB 2566

INTRODUCER: Senator Atwater

SUBJECT: Brain Tumor Research

DATE: April 22, 2006 REVISED: 04/25/06

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Garner	Wilson	HE	**Fav/1 amendment**
2.			CM	
3.			HA	
4.			WM	
5.				
6.				

Please see last section for Summary of Amendments

☐ Technical amendments were recommended
☐ Amendments were recommended
☒ Significant amendments were recommended

I. Summary:

The bill provides legislative intent regarding the need for coordination among researchers and health care providers in the effort to find cures for cancerous and non-cancerous brain tumors. The bill directs the Department of Health (DOH or department) to develop and maintain an automated, electronic, and centralized database of individuals with brain tumors.

The bill establishes the Florida Center for Brain Tumor Research (the center) within the Scripps Research Institute. The purposes of the center are to provide a central repository for brain tumor biopsies, improve and monitor brain tumor biomedical research programs within the state, facilitate funding opportunities, and foster improved transfer of brain tumor research findings into clinical trials and public use. The bill also requires the center to hold annual brain tumor biomedical technology summits in the state so researchers and providers may share biomedical research findings.

The bill creates a scientific advisory council within the center that includes biomedical researchers, physicians, and representatives from public and private universities and hospitals. Members of the council serve without compensation.

The bill includes an appropriation of $4 million from the General Revenue Fund to the

Florida Center for Brain Tumor Research for the 2006-2007 fiscal year for the purpose of funding brain tumor research and the procurement of brain tumor biopsies.

The bill creates s. 381.853, Florida Statutes.

II. Present Situation:

Brain Tumors: Descriptions and Statistics

A tumor, or neoplasm, refers to a "new growth" of cells that already exist in a certain part of the body. Many different tumors can occur in the nervous system. They often cause headaches, seizures or neurological deficits. Tumors can be either benign or malignant. Malignant tumors are referred to as cancers.

There are over 150 types of brain tumor disorders. Because of the many and varied types of brain tumors, treatment is complicated. Brain tumor treatments can consist of surgical resection or biopsy, radiation approaches, or drug treatment approaches (chemotherapy). Some tumors can be treated with modification of the body's own immune system (immunotherapy).[1]

The American Cancer Society estimates that 18,820 Americans have been diagnosed with malignant brain or spinal cord tumors in 2005 and that 12,820 of these patients will die from these malignant tumors (it is estimated that 930 of these deaths were in Florida).[2] According to the National Brain Tumor Foundation: [3]

- Each year approximately 190,000 people in the United States will be diagnosed with a primary or metastatic brain tumor.
- Brain tumors are the leading cause of Solid Tumor death in children under age 20 now surpassing acute lymphoblastic leukemia (ALL), and are the third leading cause of cancer death in young adults ages 20-39.
- Brain tumor patients, including those with certain "benign" brain tumors, have poorer survival rates than breast cancer patients.
- Metastatic brain tumors (cancer that spreads from other parts of the body to the brain) occur at some point in 10 to 15 percent of persons with cancer, and are the most common type of brain tumor. The incidence of brain tumors has been increasing as cancer patients live longer.
- In the United States, the overall incidence of all primary brain tumors is more than 14 per 100,000 people.
- Because brain tumors are located at the control center for thought, emotion and movement, their effects on an individual's physical and cognitive abilities can be devastating.
- Only 31 percent of males and 30 percent of females survive five years following the diagnosis of a primary or malignant brain tumor.

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[1] *See* Department of Neurological Surgery, University of Pittsburg. Found at: http://www.neurosurgery.pitt.edu/conditions/#S (last visited April 21, 2006)

[2] *See* the American Cancer Society's website. Found at: http://www.cancer.org/ (last visited on April 21, 2006).

[3] *See* National Brain Tumor Foundation's website. Found at: http://www.braintumor.org/newsroom/quick_facts/index.html (last visited on April 21, 2006)

- Brain tumors in children are different from those in adults and are often treated differently. Although as many as 69 percent of children with brain tumors will survive, they are often left with long-term side effects.
- Enhancing the quality of life of people with brain tumors requires access to quality specialty care, clinical trials, follow-up care and rehabilitative services. Improving the outlook for adults and children with brain tumors requires research into the causes of and better treatments of brain tumors.
- Complete and accurate data on all primary brain tumors are needed to provide the foundation for research leading to improved diagnosis and treatment and to investigations of its causes.

According to the Florida Cancer Data System, the incidence of brain cancer in Florida in 2004 was 5.45 incidents per 100,000 population;[4] however, the incident rate by age group is significantly different as demonstrated by the following table:

Age Range	Incidence Rate (per 100,000 Population)	Age Range	Incidence Rate (per 100,000 Population)
0 to 4	4.48	45 to 49	4.55
5 to 9	2.94	50 to 54	6.58
10 to 14	2.26	55 to 59	9.23
15 to 19	1.52	60 to 64	10.50
20 to 24	1.85	65 to 69	14.88
25 to 29	2.41	70 to 74	13.85
30 to 34	2.86	75 to 79	15.72
35 to 39	4.37	80 to 84	18.93
40 to 44	3.83	85 and up	12.53
All Ages		**5.45 per 100,000**	

Brain Tumor Symptoms and Treatment

Symptoms of a brain tumor can include headaches (of sufficient discomfort to disrupt sleep), seizures in a person who does not have a history of seizures, cognitive or personality changes, eye weakness, nausea or vomiting, speech disturbances, or memory loss. While these are the most common symptoms of a brain tumor, they can also indicate other medical problems.

At present, surgery is the primary treatment for brain tumors that lie within those membranes covering the brain or in parts of the brain that can be removed without damaging critical neurological functions. Because a tumor can regrow if any tumor cells are left behind, surgeons strive to remove the entire tumor whenever possible. Radiation therapy and chemotherapy, in general are used as secondary or adjuvant treatment for tumors that cannot be removed by surgery alone.

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[4] Statistics calculated are adjusted rates for all persons using 2004 provisional data. Analytical tool and statistics found at: http://www.fcds.med.miami.edu/oscripts/pub_extrates.asp (last visited on April 21, 2006)

Cancer Registries

Cancer registries collect information about the occurrence (incidence) of cancer, the types of cancers diagnosed and their locations within the body, the extent of cancer at the time of diagnosis (disease stage), and the kinds of treatment that patients receive. These data are reported to a central statewide registry from various medical facilities, including hospitals, physicians' offices, therapeutic radiation facilities, freestanding surgical centers, and pathology laboratories.

National Registries

The Centers for Disease Control and Prevention (CDC) has administered the National Program of Cancer Registries (NPCR) since 1994. Before NPCR was established, 10 states had no registry and most states with registries lacked the resources and legislative support needed to gather complete data. With fiscal year 2004 appropriations of approximately $50 million, CDC's NPCR supports central registries and promotes the use of registry data in 45 states, the District of Columbia, and the territories of Puerto Rico, the Republic of Palau, and the Virgin Islands. The CDC also is conducting special research projects such as studies to examine patterns of cancer care in specific populations. The CDC's goal is for all states to maintain registries that provide high-quality data on cancer and cancer care.

As of January 1, 2004, all cancer registrars in the United States are required to identify and abstract benign and borderline tumors of the brain and central nervous system. The collection of benign brain and central nervous system tumors is mandated by Public Law 107-260, also known as the Benign Brain Tumor Cancer Registries Amendment Act. Any central cancer registry funded by the NPCR of the CDC is required to submit benign and borderline central nervous system cases to NPCR.

The Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute will also begin collecting benign central nervous system tumors as a research priority defined by two independent agencies within the National Institutes of Health. As a result, there will be 100 percent central registry participation in this effort.

State Cancer Registries

The SEER program gathers in-depth data on cancer cases diagnosed in Connecticut, Hawaii, Iowa, New Mexico, and Utah, as well as in six metropolitan areas and several rural/special population areas. The six metropolitan SEER registries and some of the rural/special population registries submit data to NPCR's state registries. In 2001, SEER began providing additional support to four NPCR-supported state registries (California, Kentucky, Louisiana, and New Jersey).

A few of these statewide registries also collect additional information on survival after the diagnosis and initial treatments. Data collected by state cancer registries enable public health professionals to better understand and address the cancer burden. Registry data are critical for targeting programs focused on risk-related behaviors (e.g., tobacco use and exposure to the sun) or on environmental risk factors (e.g., radiation and chemical exposures). Such information is also essential for identifying when and where cancer screening efforts should be enhanced and for monitoring the treatment provided to cancer patients. In addition, reliable registry data are fundamental to a variety of research efforts, including those aimed at evaluating the effectiveness of cancer prevention, control, or treatment programs.

The Florida Cancer Registry Program

Section 385.202, F.S., provides for the establishment of a statewide cancer registry program to ensure that cancer reports are maintained and available for use in the course of any study for the purpose of reducing morbidity and mortality.

Under Florida's cancer registry requirements, specified facilities and practitioners that diagnose or suspect the existence of cancer are required to report through the Florida Cancer Data System (FCDS), such cancer incidence information as specified by Rule 64D-3.006, F.A.C., including: routine personal and demographic data, diagnosis, stage of disease at diagnosis, medical history, laboratory data, tissue diagnosis, and initial course of treatment. Facilities and practitioners required to report this information include: each facility licensed under ch. 395, F.S.; any licensed practitioner in the state that practices medicine, osteopathic medicine, chiropractic medicine, naturopathy, or veterinary medicine; each freestanding radiation therapy center as defined in ch. 408, F.S.; and any laboratory licensed under ch. 483, F.S. Failure to report this information may be cause for registration or licensure suspension or revocation.

This information is collected by FCDS, which is Florida's legislatively-mandated, population-based, statewide cancer registry. The FCDS is a joint project of DOH and the University of Miami, Miller School of Medicine. The FCDS is utilized by the state and its partners to monitor the occurrence of cancer incidence and mortality, to aid in research studies to reduce cancer morbidity and mortality, to focus cancer control activities, and to address public questions and concerns regarding cancer.

The FCDS is the single largest population-based, cancer incidence registry in the nation. Over 150,000 cases are collected from patient medical records annually. The FCDS database contains approximately 2.3 million cancer records, 3.5 million discharge records and 3.1 million mortality records. Ninety-six percent of all records in the FCDS database are histologically confirmed. Data collected and coded by the FCDS are in accordance with national standards as set forth by the North American Association of Central Cancer Registries, and the FCDS uses the International Classification of Diseases – Oncology, 3rd edition (ICD-O-3) to code primary site and morphology.

The FCDS is part of the CDC-NPCR and is nationally certified by the North American Association of Central Cancer Registries at its highest level, gold certification. Gold certification is conferred on central cancer registries that exceed all standards for completeness, timeliness and quality.

High-Impact Business Sectors

Under s. 281.108, F.S., a business sector may be designated a "high-impact" industry for purposes of economic development. This official state designation qualifies the particular industry for certain economic incentives and tax credits. The Life Sciences business sector has been designated a high-impact industry in Florida, making biotechnology, medical device and pharmaceutical companies eligible for a number of specialized incentives and tax credits.

Qualified Target Industry Tax Refunds
New or expanding businesses in targeted industries and designated corporate headquarters that serve multi-state and/or international markets are eligible for this refund. Pre-approved applicants that create new jobs paying 115 percent of the average annual area wage may receive tax refunds of up to $3,000 per new job created, or up to $6,000 per new job in an Enterprise Zone or rural county. Additional "per job" bonuses are available for businesses paying 150 or 200 percent of the average annual area wage or locating in designated "Brownfields."

Capital Investment Tax Credit
This is an annual credit against Florida corporate income tax liability. The amount of the annual credit is equal to five percent of the eligible capital costs and can be taken for 20 consecutive years. Eligible costs include all expenses incurred in the acquisition, construction, installation and equipping of a project from the beginning of construction to the commencement of operations. The annual credit is limited to a specified percentage of the project's corporate income tax liability, depending on the level of investment. For example, if a company invests $25 million in a Florida expansion project, it could be eligible for an annual credit of $1.25 million or 50 percent of the Florida corporate income tax liability generated by the project, whichever is lower, for up to 20 years. To qualify, a company must create at least 100 new jobs and invest a minimum of $25 million in the project.

High Impact Performance Incentive
This negotiated incentive is used to attract and grow major high-impact facilities. To qualify, a project in the designated high impact sector must create at least 100 new full-time jobs in Florida and make a cumulative investment of at least $100 million in a three-year period. If the facility is a research facility, the qualifications are 75 full-time jobs and a cumulative investment of $75 million.

Scripps Research Institute

Scripps Florida is an expansion of The Scripps Research Institute, the world's largest, private non-profit biomedical research facility, and is designated a high-impact sector in Florida. Scripps is recognized for its research in immunology, molecular and cellular biology, chemistry, neurosciences, autoimmune diseases, cardiovascular diseases and synthetic vaccine development. Scripps Florida will focus on biomedical research, technology development, and drug design, working to produce major drug candidates in a short period of time.

Scripps Florida is temporarily located in a 41,000 square foot building located on the Jupiter campus of Florida Atlantic University. A second 33,000 square foot building is being constructed and will be available for use in the August-September 2006 timeframe. There are currently over 160 people housed in temporary facilities, 80 percent of which are faculty and scientific staff. The rest are support personnel.

III. Effect of Proposed Changes:

Section 1. Creates s. 381.853, F.S., establishing the Florida Center for Brain Tumor Research.

Subsection (1) provides legislative findings that each year an estimated 190,000 citizens of the United States are diagnosed with cancerous and noncancerous brain tumors and that biomedical research is the key to finding cures for these tumors. While research is being conducted around the state, there is a lack of coordinated efforts among researchers and health care providers. The Legislature further finds that there is a significant need for a coordinated effort to achieve the goal of curing brain tumors and that the biomedical technology sector meets the criteria of a high-impact sector.

Subsection (2) states that it is the intent of the Legislature to establish a coordinated effort among the state's public and private universities and hospitals and the biomedical industry to discover brain tumor cures and develop brain tumor treatment modalities. Moreover, it is the intent of the Legislature to expand the state's economy by attracting biomedical researchers and research companies to the state.

Subsection (3) requires DOH to develop and maintain a brain tumor registry that is an automated, electronic, and centralized database of individuals with brain tumors. Individuals, or their guardians or representatives, may refuse to have the individual's information released to the registry by signing a form obtained from DOH. Such refusal must be noted in the registry.

Subsection (4) establishes the Florida Center for Brain Tumor Research within the Scripps Research Institute. The purpose of the center is to provide a central repository for brain tumor biopsies from individuals throughout the state, improve and monitor biomedical research within the state, facilitate funding opportunities, and foster improved technology transfer of brain tumor research findings into clinical trials and widespread public use. The goal of the center is to find cures for brain tumors.

The center must hold an annual brain tumor biomedical technology summit in the state to which physicians and biomedical researchers from the state's public and private universities and teaching hospitals are invited to share research findings. Summit attendees will cover the costs of such attendance or obtain sponsorship for such attendance.

The center will encourage clinical trials in the state on research that holds the promise of curing brain tumors. The center will facilitate partnerships between researchers, treating physicians, and hospitals for the purpose of sharing new techniques and new research findings, as well as coordinating the voluntary donation of brain tumor biopsies.

The center will facilitate the formation of partnerships between researchers, physicians, and hospitals in the state. The center will be funded through private, state, and federal sources.

Subsection (5) establishes within the center a scientific advisory council that includes biomedical researchers, physicians, and representatives from public and private universities and hospitals. The council will meet at least annually and consist of representatives from:

- The Scripps Research Institute;
- A teaching hospital as defined in s. 408.07, F.S.;
- Public and private state universities;
- The Department of Health; and,
- The Florida Medical Association.

Council members will serve staggered four-year terms and will serve without compensation, and each organization represented must cover all expenses of its representative.

Subsection (6) authorizes DOH to adopt, repeal, and amend rules relating to the center and the administration of the brain tumor registry. Such rules may include procedures for participating in brain tumor research and for providing access to confidential information necessary for brain tumor investigations. For the purposes of the brain tumor registry, the rules may include procedures for a health care practitioner and researcher to obtain authorization to use the brain tumor registry and methods for an individual or guardian to elect not to participate in the brain tumor registry.

Section 2. Appropriates the sum of $4 million from the General Revenue Fund to the Florida Center for Brain Tumor Research for the 2006-2007 fiscal year for the purpose of funding brain tumor research and funding for the procurement of brain tumor biopsies.

Section 3. The bill takes effect on July 1, 2006.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

Senate Bill 2564, which is linked to this bill, creates a public records exemption for the Florida Center for Brain Tumor Research. Implementation of s. 381.853(4), F.S., created by this bill to establish the Florida Center for Brain Tumor Research, however, is not contingent upon the passage of a public records exemption.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Private universities, hospitals and biomedical firms researching brain tumor cures and developing brain tumor treatment modalities would be able to access up to $4 million through the Florida Center for Brain Tumor Research.

C. Government Sector Impact:

According to DOH, the department will need additional funding to develop a specific automated, electronic, and centralized database of individuals with brain tumors and to provide staffing necessary to maintain quality, completeness and timeliness of the registry data; develop and maintain rules; and to participate in the Advisory Council meetings and activities. The department estimates that these requirements would cost $208,479 to administer in FY 2006-07, and $196,584 to administer in FY 2007-08.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill does not require any entity to report the identity of individuals with brain tumors to the DOH brain tumor registry.

The bill does not specify the purpose or duties of the scientific advisory council in the Florida Center for Brain Tumor Research.

Florida currently has a statewide cancer registry that collects similar data that would be collected through the brain tumor registry established in this bill. It is unclear whether the same information is required to be sent to both registries, and if so, how the two registries will be required to coordinate so that data is not lost or duplicated.

VIII. Summary of Amendments:

Barcode 874260 by Health Care:
This is a delete everything amendment. The amendment: provides legislative findings and legislative intent; establishes the Florida Center for Brain Tumor Research (the center) within the Evelyn F. and William T. McKnight Brain Institute of the University of Florida; specifies activities and the purpose of the center; requires the center to develop and maintain a brain tumor registry; allows individuals to refuse to participate in the registry; specifies that grants must be awarded on a competitive basis; requires that the center hold an annual biomedical summit to exchange information on brain tumor research; requires the center to encourage clinical trials and facilitate the practical application of research; requires the center to submit an annual report to the Governor and the Legislature recommending legislative changes to foster brain tumor research and training; establishes a scientific advisory council within the center; specifies representation and duties of the advisory council; provides an effective date.