bankheadcoley
Florida Biomedical Research Program

2006
Annual Report

For questions or to request additional copies of this report, please contact Florida Biomedical Research Programs in the Office of Public Health Research, (850) 245-4585.

William G. "Bill" Bankhead Jr. and David Coley Cancer Research Program
Inaugural Annual Report
July – December 2006

Submitted to

The Governor
The President of the Senate
The Speaker of the House of Representatives

and

The Florida Center for Universal Research to Eradicate Disease

by

The Secretary of the Department of Health
State of Florida

December 15, 2006

Executive Summary

On July 1, 2006 Florida's William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (the Program) under section(s) 381.922, *Florida Statutes (F.S.)* officially began preparations to join the race to cure cancer in all its forms. The Program was made possible by a four-year funding appropriation of $9 million per year by the 2006 Florida Legislature and is already only days away from making its inaugural investment in building a portfolio of biomedical research projects that show great promise in advancing progress towards cancer cures.

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With the establishment of this program, the state of Florida is launching a committed effort to save the lives of our friends and family, to reduce the state's inordinately high cancer burden, and to make this state a world-class leader in cancer research and treatment. It calls for a coordinated, collaborative approach to biomedical research as an essential strategy for the prevention, treatment, and cure of cancer-related diseases.

Responding to the urgency of the need and a desire to engage the Florida research community rapidly, Program staff and the Florida Biomedical Research Advisory Council held an anticipatory planning session in June to define the grant mechanisms for the inaugural year. Because of this focused effort, the first Call for Grant Applications occurred in August 2006 with a goal of making awards in January 2007. Applicants submitted 47 proposals in September and October from research entities including seven public and private universities and two non-profit research institutions. The peer review process was completed in time for the Advisory Council to make funding recommendations in mid-November. Thirty-three awards were announced in December and funded projects will begin in January 2007. Further details on awards were not available at press time.

The two types of mechanisms are Bridge Grants and Shared Instrument Grants. Bridge Grants will provide interim support for promising cancer-related, investigator-initiated research projects that have been highly rated by national panels of peer reviewers in recent federal competitions but not funded due to budgetary constraints. Shared Instrument Grants will support Florida investigators who are conducting cancer-related research by improving access to state-of-the-art research instruments that can only be justified on a shared-use basis and for which meritorious cancer research projects are identified.

On the heels of the release of the 2006-2007 Call for Grant Applications, the Advisory Council once again faced the challenge of defining and developing grant mechanisms for the next annual round of funding. The 2007-2008 Call for Grant Applications offers to sponsor new grant mechanisms including Specialized Program of Research Excellence (SPORE) Planning Grants, New Investigator Research Grants, and a Special Emphasis Project, and continue the one year Bridge Grant Mechanism. This call, released in mid-December will fund awards to begin in July of 2007.

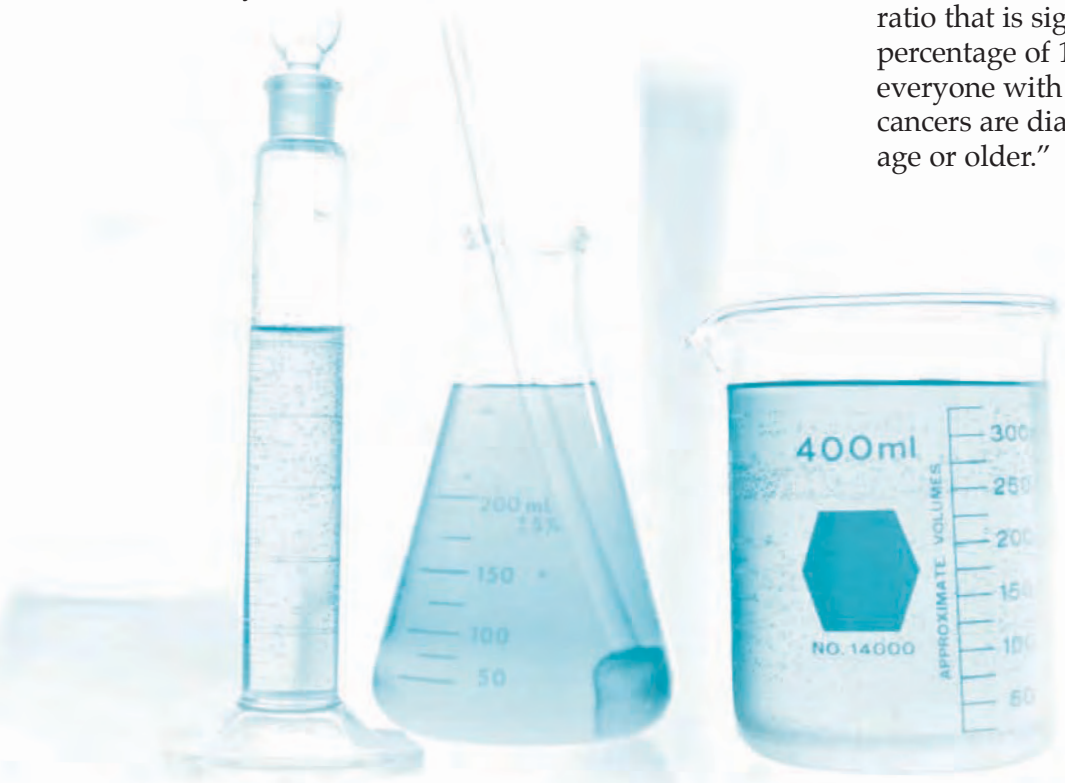
In the following pages you will see that the Program staff and the state's community of scientists and clinical practitioners are now poised at the starting block, ready to begin delivering on the challenges issued only months ago by our Florida lawmakers.

On your mark; get set; GO!

Program Background

On June 13, 2006, Governor Bush signed into law legislation presented by the Florida House and Senate authorizing the investment of $120 million in biomedical research in Florida over a four-year period. The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (also known as the Bankhead-Coley Cancer Research Program) is an important component of this investment. Beginning in fiscal year 2006-2007, Florida lawmakers agreed to appropriate the sum of $9 million annually from recurring funds in the General Revenue Fund in response to compelling evidence that more cancer research and improved cancer treatment is necessary in the state.

Fresh in their minds were the losses in 2005 of two of their colleagues to cancer. Bill Bankhead was a 20-year veteran of the Florida Legislature in both the House and Senate. David Coley, the late husband of Representative Marti Coley, was a longtime legislative staffer who succumbed to liver cancer during his initial session as an elected member of the Florida House of Representatives. While honoring these two men in the name of the Program, this legislative action recognizes that too many Floridians fall victim to this dreaded disease.



According to statistics published by the American Cancer Society[1], Florida ranks second in the nation in cancer incidence and mortality. The numbers indicate that the lives of nearly 99,000 Floridians and their families changed suddenly in 2006 when they received new cancer diagnoses. These brothers, sisters, parents, spouses, friends, grandparents, sons, and daughters joined more than 500,000 of their Florida neighbors in the frightening and costly battle against the disease. Roughly 40,000 citizens of our state lost that battle during the last 12 months.

In a position paper prepared for the 2006 state legislative session[2], the Florida Division of the American Cancer Society points out that, in addition to the human toll, our state is facing an accelerating financial burden associated with cancer treatment due to our growing and aging population. According to that paper, "Thirty-five percent of Floridians (about 5.6 million people) are considered to be at 'high risk' for cancer. The U.S. Census estimates that by 2025, 24% of the population of Florida will be over the age of 65. More than 17.6% of Florida's current population consists of seniors 65 years of age and older, a ratio that is significantly higher than the national percentage of 12.4%. Cancer risk increases for everyone with age. Seventy-seven percent of all cancers are diagnosed in individuals 55 years of age or older."

The paper goes on to identify a concern that, in spite of Florida's disproportionately large cancer challenge, the state is significantly lagging in attracting important funding to support cancer research in the state. It states, "Florida will continue to fall woefully behind other states in its ability to attract the best research talent and provide cancer patients with the cutting-edge care they deserve." As evidence of this concern, in 2005 fifteen states received a larger share than Florida of the $4.7 billion

awarded by the National Cancer Institute (NCI) cancer research grants and contracts[3]. Of 61 Cancer Centers supported by NCI funding (P30 Core awards) throughout the nation that year, only one Florida institution was represented — the H. Lee Moffitt Cancer Center and Research Institute — and its award of $2.3 million was significantly less than the average of $4.0 million[4]. Florida researchers seeking to right this imbalance are finding it increasingly difficult to compete successfully for NCI funding. NCI is seeing dramatically increasing numbers of funding requests from across the nation, all vying for relatively constant dollars. Over the last four years, the success rate for winning NCI Research Project Grants has plummeted from 28.4% in 2001 to 19.2% in 2005[5]. Without significant federal research budget increases in the near term, this trend is likely to continue.

The creation of the Bankhead-Coley Cancer Research Program represents a vital, timely investment by the Florida House and Senate. Its specific purpose is to advance progress toward cures for cancer through grants awarded in a peer-reviewed, competitive process. Accompanying this investment are clear directives to extend equal opportunity and access to funding to all qualified investigators throughout the state; to fund the most meritorious projects as determined by a scientifically rigorous, unbiased review process; and to emphasize productive collaborations among institutions, researchers, and community practitioners. The Program has a discrete window of four years to demonstrate measurable gains against program goals, with future support conditional upon the conclusion of a review of program performance, outcomes, and financial management during the 2010 Regular Session of the Legislature.

According to the American Cancer Society, Florida ranks second in the nation in cancer incidence and mortality. In 2006, an estimated 99,000 Floridians will receive new cancer diagnoses.[1]

Newly embodied in s. 381.922, *F.S.* — William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (included in Appendix A), the Program was created effective July 1, 2006 within the Florida Department of Health, and is supported by the advice and counsel of the Florida Biomedical Research Advisory Council. Consistent with their intent to stimulate a synergistic statewide focus to the pursuit of cancer cures, the Legislature directly linked the goals of the Program to those already established for the Florida Cancer Council in s. 381.921, *F.S.* — Florida Cancer Council Mission and Duties, (included in Appendix B).

It is a fact that biomedical research in the U.S. during the last thirty years has enabled more people to live with, rather than die from, cancer. In addressing a U.S. House Subcommittee in April 2006, Dr. John Neiderhuber, NCI Deputy Director testified: "Today there are nearly 10 million cancer survivors in the United States compared to approximately 3 million cancer survivors in 1971 when the National Cancer Act was established. Also, in 1971 fewer than half of those found to have cancer lived 5 years beyond their diagnosis; today the 5 year survival rate is 64% for adults and 79% for children aged 14 or younger. The latter figure is truly remarkable given how few children survived even a couple of years after being diagnosed in the early 1970s."[6]

Many talented and productive researchers and clinical practitioners in Florida have contributed to making these gains possible during the last three decades, and a number of high-profile cancer-related programs and funding strategies have been created in the state over the years. In 2006, with the Bankhead-Coley Cancer Research Program coming off the starting block, many more current and future Florida-based researchers will have the means with which to deliver their best work.

Program Goals

Section 1 of the enabling legislation for the Bankhead-Coley Cancer Research Program[7] explicitly describes three important elements of the legislative intent in creating the program:

- To provide funding to support grants for biomedical research in this state with the anticipation that sustained funding for biomedical research over a period of years will lead to an alleviation of human suffering from diseases such as cancer
- To dramatically reduce this state's inordinately high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in this state, making this state a world class leader in cancer research and treatment
- To stimulate dramatic economic development, particularly in the biotechnology industry, through investment in this state's biomedical research

Program staff accepts these elements as the framework for establishing goals that are more specific, along with emphasis on the following:

1. Significantly expand cancer research capacity in the state by:
    a. Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state
    b. Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state
    c. Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support
    d. Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations
    e. Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research
    f. Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research
2. Improve both research and treatment through greater participation in clinical trials networks by:
    a. Identifying ways to increase adult enrollment in cancer clinical trials
    b. Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials
    c. Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state
    d. Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks
3. Reduce the impact of cancer on disparate groups by:
    a. Identifying those cancers that disproportionately impact certain demographic groups
    b. Building collaborations designed to reduce health disparities as they relate to cancer

Progress Toward Goals

The first challenge accepted by Program staff was to develop and deploy a funding cycle normally spanning 12 months within a greatly accelerated timeframe, so that fiscal year 2007 funds could be invested as soon as possible without compromising the quality of the application solicitation, review, and award process.

The second challenge undertaken was to concurrently determine grant mechanisms, plans, and schedules for the fiscal year 2008 program, with awards to begin July 1, 2007.

2006 Inaugural Program

In anticipation of the July 1, 2006 effective date of the Bankhead-Coley Cancer Research Program, the Department of Health Office of Public Health Research convened a meeting of the Florida Biomedical Research Advisory Council in Tampa in June 2006. This meeting produced a collection of recommendations for grant mechanisms and plans that would permit Program sponsored research to begin in January 2007. The outcome of this meeting was the basis for the preparation of an inaugural Call for Grant Applications. To publicize the availability of funding rapidly, nearly 700 individuals received pre-announcement e-mails in July with general information about the planned Program offerings as well as notification on August 15, 2006 of the release of the official Call for Grant Applications.

In pursuit of Program goals, Program staff and the Advisory Council agreed to offer two grant mechanisms for the first year: Bridge Grant and Shared Instrument Grants.

Bridge Grants

The intent of the Bridge Grant mechanism is to provide interim support for promising cancer-related, investigator-initiated research projects that have been highly rated by national panels of peer reviewers in recent federal competitions but not funded due to budgetary constraints. Allowable federal competitions included programs of the National Institutes of Health, including the National Cancer Institute, the Department of Defense Congressionally Directed Medical Research Programs for Breast Cancer Research or Prostate Cancer Research, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

The Advisory Council cited several reasons for recommending the Bridge Grant mechanism.

- Well-managed national panels of qualified peer reviewers would already have evaluated eligible proposals
- The interval of time required for comprehensive proposal preparation is shorter, since eligible proposals would already have been prepared
- The burden on applicants to prepare another customized proposal would be greatly reduced
- This form of award may increase the likelihood that an investigator will be successful in a subsequent proposal submission to the federal agency

Conceived as an experiment, this mechanism represented an innovative approach to identifying high potential research within the state since the absence of data regarding the number of eligible applicants made it difficult to predict the response. It was accompanied by the challenge of fairly integrating disparate rating systems among unrelated federal competitions. Based on a strong, shared belief that the benefits outweighed the challenges, Council members expressed a commitment to find reasonable ways to make this offering work.

The Call for Grant Applications invited all Florida researchers with evidence of an investigator-initiated cancer related research project rated in the top 30th percentile by a federal agency on or after September 15, 2005 to submit an application for Bridge Grant funding. While all were required to be cancer related, projects involving basic science, translational or clinical research, medical devices, bioinformatics, epidemiology, or human behavior were explicitly solicited. Proposals were required to demonstrate a clear relationship between the proposed research and the advancement toward cures for cancer. Investigators at all levels of experience were eligible to apply for a one-year Bridge Grant award of up to $200,000. New investigators under the mentorship of a senior investigator were eligible to apply for two years of funding for a total of up to $400,000. All awardees will be required to show evidence that another proposal involving related research has been submitted to the federal agency by December 2007.

The project selection criteria adopted by the Program consisted of a relative ranking of scientific merit based on an algorithm designed to integrate ratings assigned by different federal programs, and the appropriateness of the plan for research using Bridge Grant funding. When differentiating between otherwise equivalent applications, proposals that foster collaboration among institutions, researchers, and community practitioners, including clinical trials involving cancer patients and related networks received preference.

Bridge Grants will begin on or about January 1, 2007.

Shared Instrument Grants

The intent of the Shared Instrument Grant mechanism is to support Florida investigators who are conducting cancer-related research by improving access to state-of-the-art research instruments that can only be justified on a shared-use basis and for which meritorious cancer research projects are identified.

The Advisory Council judged the Shared Instrument Grant to be especially appropriate during the first year of the Program for several reasons:

- It will enable Florida institutions to fill a number of existing gaps in access to specialized equipment critical to the conduct of leading edge cancer research during the next three years of the Program and, in some cases, beyond
- Shared access to specialized instrumentation will foster collaborative cancer-related research and increase the likelihood of competing more successfully for larger national grants and contracts
- The availability of a larger network of state-of-the-art instruments will attract more scientists to conduct cancer-related research at Florida institutions

The Call for Grant Applications solicited proposals from any university or established non-profit research institution in Florida for a single instrument, a large system of instruments, or multiple instruments that share a common or specific research focus. To assure the distribution of state-of-the-art equipment throughout the state, Shared Instrument Grant applications were limited to two per institution, each requesting support for different equipment. Applicants were required to provide a compelling case illustrating how the requested acquisition will further the search for cures to cancer, as evidenced by a minimum of three representative cancer-related projects that would benefit from access to the instrumentation. Justification was required for why

the equipment is necessary and not simply more convenient. In addition, applicants submitted a management plan tracked by an advisory committee to schedule instrument access and provide ongoing maintenance and support.

Awards range from $100,000 to $500,000 for up to 12 months for eligible project costs including instrument upgrade or initial purchase, installation, commissioning, and calibration. Awardees will be responsible for making annual reports to the Program for a maximum period of five years, or less depending on the useful life of the equipment. These will include the value of additional grant awards for cancer related research that utilize the instruments as well as a list of cancer-related publications in peer-reviewed journals based on research performed using the equipment.

Shared Instrument Grants will begin on or about January 1, 2007.

Preliminary Results

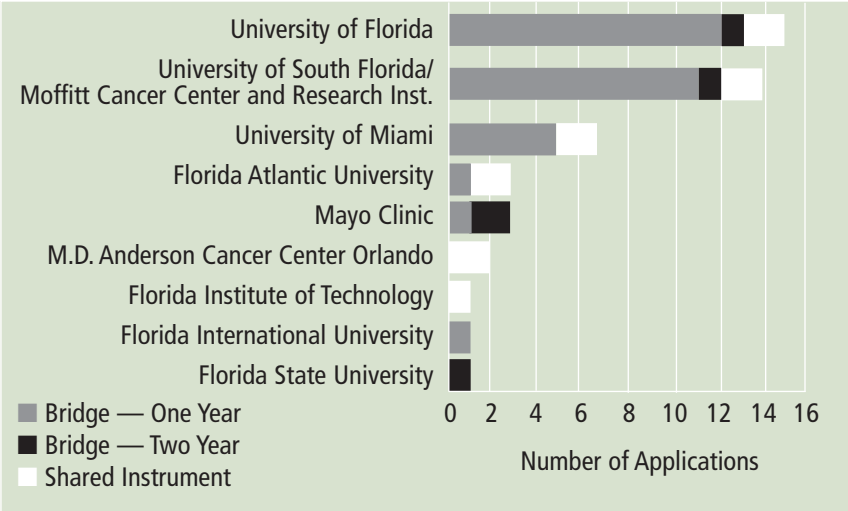
In response to the 2006-2007 Call for Grant Applications, a total of 47 eligible applications were received, requesting a total of $11,847,589. The table to the right provides a breakdown of the requests across the offered grant mechanisms.

2006 Applications by Grant Type

Grant Mechanism	Applications Received	Percent Distribution	Requested Funding Amounts
Bridge Grant – One year	31	66%	$5,020,998
Bridge Grant – Two year	5	11%	$1,805,733
Shared Instrument Grant	11	23%	$5,020,858
Total	47	100%	$11,847,589

The applicants represented nine Florida research institutions, with applications from the University of Florida and the University of South Florida / Moffitt Cancer Center and Research Institute accounting for 29 of the 47 submissions, or 62 percent.

2006 Applications by Institution



2006 Bridge Grant Applications by Federal Agency

Federal Agency	Number of Applications
National Cancer Institute	23
Department of Defense Congressionally Directed Medical Research Program	4
National Heart, Lung, and Blood Institute	2
National Institute of Diabetes and Digestive and Kidney Disease	2
National Center for Complementary and Alternative Medicine	1
National Institute on Aging	1
National Institute of Allergy and Infectious Disease	1
National Institute of Child Health and Human Development	1
National Institute of Dental and Craniofacial Research	1
Total	36

Bridge Grant Applications

Applicants presented high-scoring but unfunded cancer-related research projects from nine federal competitions as shown above.

While the results of the federal peer review process served as the primary indicator of scientific merit, Program staff arranged for an abbreviated peer review of each eligible application to assist in determining the fit with programmatic interests. Three national subject matter experts evaluated each application for the strength of the cancer relationship, the reasonableness of the investigator effort and budget for work commitments with the Bridge Grant, and the degree of collaboration represented.

Funding recommendations were received in mid-November from the Biomedical Research Advisory Council, and 26 Bridge Grant awards were announced in December so that sponsored research may begin in January 2007.

Shared Instrument Grant Applications

The Program received eleven shared instrument proposals from six universities and institutions.

Eligible applications underwent a peer review process consisting of five national subject matter experts who assigned an overall rating to each proposal based on their assessment of the:

- Technical merit of the proposed research that would benefit from access to the requested instrumentation
- Apparent need for the equipment
- Likelihood that the projected instrument utilization would be realized
- Quality of the management plan for overseeing the equipment use, including the strength of the institutional commitment to provide ongoing support
- Degree of collaboration represented

To compensate for the fact that reviewers did not engage in a discussion to arrive at consensus on an overall rating, Program staff averaged the middle three scores to create each proposal's final peer review score.

In mid-November, the Biomedical Research Advisory Council considered each of these scores, along with associated reviewer assessments of the cancer relationship and degree of collaboration for each proposal. The Advisory Council recommended seven Shared Instrument Grant awards to the Secretary of Health.

Plans for 2007-2008 Program

In preparation for the upcoming 2007–2008 funding cycle, the Advisory Council and Program staff met via teleconference in August and in person in September in Tampa to deliberate and form recommendations for competitive grant mechanisms and eligibility requirements. Based on the outcome of these sessions, a Call for Grant Applications for four grant mechanisms is underway for funding beginning July 1, 2007.

Specialized Program of Research Excellence (SPORE) Planning Grant

The objective of this grant is to assemble and prepare strong interdisciplinary teams of Florida researchers to compete successfully for very large SPORE grants offered by the National Cancer Institute[8] (up to $2.5 million per year for up to five years). Offered annually since 2000, the intention of NCI SPORE grants is to improve the screening, detection, diagnosis, treatment, and prevention of an organ-specific cancer (or related group of cancers). None of the 58 active SPORE projects currently funded by NCI are in Florida. With a requirement for translational projects involving collaboration among investigators conducting basic and applied research, the goals of the SPORE mechanism clearly dovetail with the interests of the Bankhead-Coley Cancer Research Program. Program investments in SPORE Planning Grant awards of up to $1 million over a period of up to three years will greatly leverage Program funds when sponsored teams secure more sizeable federal awards during the next decade.

Bridge Grant

Based on the response to the inaugural Call for Grant Applications, the Program decided to repeat this offer for investigators of all experience levels. Applicants must provide evidence of promising cancer-related, investigator-initiated research projects highly rated by national panels of peer reviewers in recent federal competitions but not funded due to budgetary constraints. By providing a safety net to counterbalance the delay in winning federal funding, these Bridge Grants will not only produce research results, but also attract and sustain talented scientists and clinicians in Florida. Up to $200,000 will be awarded for a maximum period of one year.

New Investigator Research Grant

The intention of this award is to complement the Bridge Grant award in increasing the research capacity at Florida institutions by offering special support for investigators in the early stages of an independent investigative career. Applicants are required to work under the guidance of an experienced mentor on high-potential projects spanning a period of up to three years. While all cancer-related applications are accepted, the Call for Grant Applications expressed a special interest in receiving proposals addressing efforts to improve research and/or treatment through greater participation in clinical trial networks, and efforts to reduce the impact of cancer on disparate groups. Annual awards will be $125,000 each with up to two yearly renewals extended for a total maximum award of $375,000.

Special Emphasis Project: Identification of Barriers to Participation of Florida Cancer Patients in Clinical Trials

In order to obtain a framework for future mechanisms of support, the Program is requesting proposals for a comprehensive study intended to yield insights into the reasons contributing to the very low patient participation rate in clinical trials in the state. Applicants must propose methodologies that will capture both patient and provider perspectives as well as those of disparate populations. The Call for Grant Applications emphasized a preference for projects involving inter-institutional collaboration. The plan is to give one award for up to $500,000 for a period of up to two years.

A pre-announcement containing high level information about these grants and the associated eligibility requirements was broadcast via e-mail in mid-November to a list of approximately 700 interested parties throughout the state. The 2007–2008 Call for Grant Applications, released in mid-December is available at the Florida Biomedical Research Program website, www.floridabiomed.com.

Biomedical Research Advisory Council

The Biomedical Research Advisory Council is adjunct to the Department of Health under s. 215.5602, *F.S.* — James & Esther King Biomedical Research Program (included in Appendix C). Effective July 1, 2006, the Advisory Council expanded from nine to eleven members, consisting of the following delegates:

- One representative of the Florida Division of the American Cancer Society
- One representative of the Florida/Puerto Rico Affiliate of the American Heart Association
- One representative of the American Lung Association of Florida
- Four members appointed by the Governor
  - Two members with expertise in the field of biomedical research
  - One member from a research university in the state
  - One member representing the general population of the state
- Two members appointed by the President of the Florida Senate
  - One member with expertise in the field of behavioral or social research
  - One representative from a cancer program approved by the American College of Surgeons
- Two members appointed by the Speaker of the House of Representatives
  - One member from a professional medical organization
  - One representative from a cancer program approved by the American College of Surgeons

The Advisory Council charge is to award grants for cancer research through the Bankhead-Coley Cancer Research Program. Among its other responsibilities, the Advisory Council also advises the Secretary of the Department of Health and the Office of Public Health Research as to the direction and scope of the Program and assists in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of its operation.

Appointments for eight new members to the Advisory Council occurred in 2006, with each member serving three-year terms.

A list of members, including the seat held, appears on the following page.

Biomedical Research Advisory Council Members

Edward R. Block, M.D.
Distinguished Professor and Chair
Department of Medicine
University of Florida
Seat: American Lung Association
Appointed: July 1, 2000

Richard J. Bookman, Ph.D.
Executive Dean for Research &
Research Training
Miller School of Medicine
and Vice Provost for Research
University of Miami
Seat: American Heart Association
Appointed: July 1, 2000
Advisory Council Chair

Nikolaus S. Gravenstein, Ph.D.
Professor and Chair
Department of Anesthesiology
University of Florida
Seat: Biomedical Research
Appointed: February 27, 2006

Myra Hurt, Ph.D.
Associate Dean, Research and
Graduate Programs
Professor
Department of Biomedical Sciences
College of Medicine
Florida State University
Seat: Research University
Appointed: February 27, 2006

Albert Latimer, B.B.A.
Vice President
External Affairs
Enterprise Florida, Inc.
Seat: General Public
Appointed: February 27, 2006

Daniel Morris, M.D.
Medical Physician
Medical Oncology and
Hematology
Naples Medical Center
Seat: Senate-Cancer Program (ACoS)
Appointed: July 17, 2006

Sigurd Normann, M.D., Ph.D.
Professor
Pathology, Immunology and
Laboratory Medicine
University of Florida
Seat: American Cancer Society
Appointed: July 1, 2000

Penny Ralston, Ph.D.
Dean and Professor
College of Human Sciences
Florida State University
Seat: Senate-Behavioral/
Social Research
Appointed: July 17, 2006

Mary Lou Sole, R.N., Ph.D.,
C.C.R.N., F.A.A.N.
Professor, School of Nursing
College of Health and
Public Affairs
University of Central Florida
Seat: House -
Professional Medical Organization
Appointed: February 27, 2006

Herbert Weissbach, Ph.D.
Distinguished Research Professor
and Director, Center for Molecular
Biology and Biotechnology
Department of Biological Sciences
Florida Atlantic University
Seat: Biomedical Research
Appointed: February 27, 2006
Advisory Council Vice-Chair

VACANT
Seat: House – Cancer Program (ACoS)

Program Operations

Administrative Costs

The Program by statute[9] can spend up to 10 percent of the funds appropriated for administrative expenses. The challenge of administering both the full inaugural funding cycle and all pre-award activities supporting the second year of Program operations during FY07 caused the Program to consume the full administrative expense allowed. On a one-time basis, the department has committed to cover expenses exceeding the limit, should it become necessary. Program staff is committed to holding administrative expenses in subsequent years of operation to 10 percent or below in order to maximize the funding devoted to grants. Economies in labor and program infrastructure gained by managing the Bankhead-Coley Cancer Research Program in tandem with its sister program, the James & Esther King Biomedical Research Program are proving to be a significant benefit in ensuring this outcome.

The data in the table *(left)* portrays the most recent estimate of administrative expenses for the current fiscal year.

Value of Grants to be Awarded ($ Million)

Fiscal Year	Appropriation	Budget For New Grant Awards	%	Budget for Administrative Expenses	%
2006-2007	$9.0	$8.1	90.0%	$0.9	10.0%

Note: Money that is obligated but not disbursed by the end of the fiscal year may be certified forward to pay out multi-year grants in future years.

Program Administration

The Office of Public Health Research within the Florida Department of Health manages the Bankhead-Coley Cancer Research Program. In addition to support from the Biomedical Research Advisory Council, the Department of Health relies on the assistance of a contracting partner, Lytmos Group, LLC, in matters of program oversight and administration.

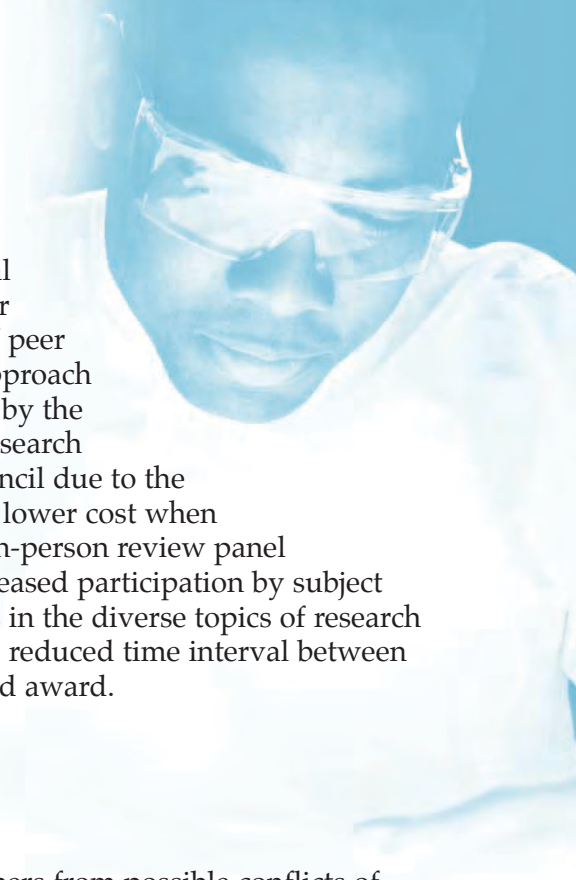
The Office of Public Health Research has designated a Program Manager who is responsible for:

- Working with the Advisory Council to develop Program policy, research grant programs and initiatives, evaluate Program effectiveness, and review long-term goals
- Managing the budget to ensure appropriate use of trust fund monies
- Procuring and managing any service contracts
- Overseeing the award and payment process
- Monitoring existing grants for progress and use of funds.

Lytmos Group provides consulting, business, and technology solutions for the grant-making industry. Their delivery of effective processes and innovative solutions helps biomedical research grant programs such as the Bankhead-Coley Cancer Research Program and the James & Esther King Biomedical Research Program improve grant program performance by reducing the burden of administrative functions and at the same time introducing best-practice solutions.

Lytmos provides the following services in support of the Bankhead-Coley Cancer Research Program:

- Program Development — Funding cycle and call for grants preparation, development and refinement of Program policies and procedures and Program materials
- Application Processing — Acceptance and processing of online applications, including administrative review for compliance with call requirements
- Peer Review Management — Reviewer recruiting, panel & review assignments, and development of evaluation materials
- Decision Support — Competition analysis and reporting, funding decision aides, and Biomedical Research Advisory Council support
- Administrative and Programmatic Monitoring — Financial and progress report evaluations; awardees' compliance with human and animal use assurances; grantee support for project, budget, or key personnel changes; financial and scientific overlap monitoring; and continuation request processing
- Program Evaluation and Improvements — Ongoing monitoring and implementation of process and performance enhancements
- Technical Support — Web site development and maintenance, automated application processing grant management systems support, and grantee technical assistance



Scientific Peer Review Process

Scientific merit and fit with the Program goals, as determined by an external evaluation process to ensure objectivity, form the basis for grant awards. The scientific and technical merit was determined through independent evaluations by qualified subject matter experts from outside of the state of Florida with specific expertise in each application topic. Reviewers are nationally prominent individuals drawn from various sectors in the life sciences field including universities, government agencies, and industry. Payment of modest honoraria occurs for review services. Review assignments are made with careful attention to the avoidance of conflict-of-interest.

Among several alternatives for the conduct of peer review, this approach was endorsed by the Biomedical Research Advisory Council due to the advantages of lower cost when compared to in-person review panel meetings, increased participation by subject matter experts in the diverse topics of research proposed, and reduced time interval between application and award.

Award Selection

In mid-November, the Biomedical Research Advisory Council considered the outcome of the peer review evaluation regarding scientific merit, cancer relatedness, and degree of collaboration as well as categories of research (e.g. basic science, translational/clinical research, bioinformatics, and pharmaceutics) to rank the entire pool of applicants and develop funding recommendations within budget levels provided by Program staff. This process was blind to protect Advisory Council members from possible conflicts of interest by redacting the names of principal investigators, institutions, and even proposal titles during deliberations.

Advisory Council recommendations were presented to the Secretary of Health for a final funding decision. Each applicant received results of the competition in December and access to a report summarizing the Program's evaluation of the submitted application.

Recommendations for Policy Change

As solicited in the enabling legislation[10], the Department of Health in concert with the Biomedical Research Advisory Council wishes to put forth the following recommendation to the Legislature to further the purpose of the Program.

Stagger the appointments to the Biomedical Research Advisory Council in order to maintain continuity in institutional knowledge in advising the Program

With a turnover of six seats and the addition of two new seats during 2006, the Program relied heavily on the three incumbent representatives of the American Heart Association, American Lung Association, and American Cancer Society to represent the history and past practices of the Advisory Council to eight new members. On multiple occasions scheduling conflicts prevented one or more of these members from participating in Council meetings. When faced with making key Program recommendations, new members experienced extraordinary demands to absorb historical information or proceeded with limited insight into past Council rationale.

Appendix A. Section 381.922, *Florida Statutes* — William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program

(1) The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, which may be otherwise cited as the "Bankhead-Coley Program," is created within the Department of Health. The purpose of the program shall be to advance progress towards cures for cancer through grants awarded through a peer-reviewed, competitive process.

(2) The program shall provide grants for cancer research to further the search for cures for cancer.
   (a) Emphasis shall be given to the goals enumerated in s. 381.921, as those goals support the advancement of such cures.
   (b) Preference may be given to grant proposals that foster collaborations among institutions, researchers, and community practitioners, as such proposals support the advancement of cures through basic or applied research, including clinical trials involving cancer patients and related networks.

(3) (a) Applications for funding for cancer research may be submitted by any university or established research institute in the state. All qualified investigators in the state, regardless of institutional affiliation, shall have equal access and opportunity to compete for the research funding. Collaborative proposals, including those that advance the program's goals enumerated in subsection (2), may be given preference. Grants shall be awarded by the Secretary of Health, after consultation with the Biomedical Research Advisory Council, on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:
      1. Investigator-initiated research grants.
      2. Institutional research grants.
      3. Collaborative research grants, including those that advance the finding of cures through basic or applied research.
   (b) In order to ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the Secretary of Health, in consultation with the council, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.
   (c) The council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest. A member of the council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement. Meetings of the council and the peer review panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

(4) By December 15 of each year, the Department of Health shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report indicating progress towards the program's mission and making recommendations that further its purpose.

(5) Beginning in fiscal year 2006-2007, the sum of $9 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for purposes of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program and shall be distributed pursuant to this section to provide grants to researchers seeking cures for cancer, with emphasis given to the goals enumerated in s. 381.921 From the total funds appropriated, an amount of up to 10 percent may be used for administrative expenses.

(6) By June 1, 2009, the Division of Statutory Revision of the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of this section, which is scheduled to expire January 1, 2011.

(7) The Legislature shall review the performance, the outcomes, and the financial management of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program during the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.

(8) This section expires January 1, 2011, unless reviewed and reenacted by the Legislature before that date.

History.—s. 8, ch. 2006-182.

Appendix B. Section 381.921, *Florida Statutes* — Florida Cancer Council Mission and Duties

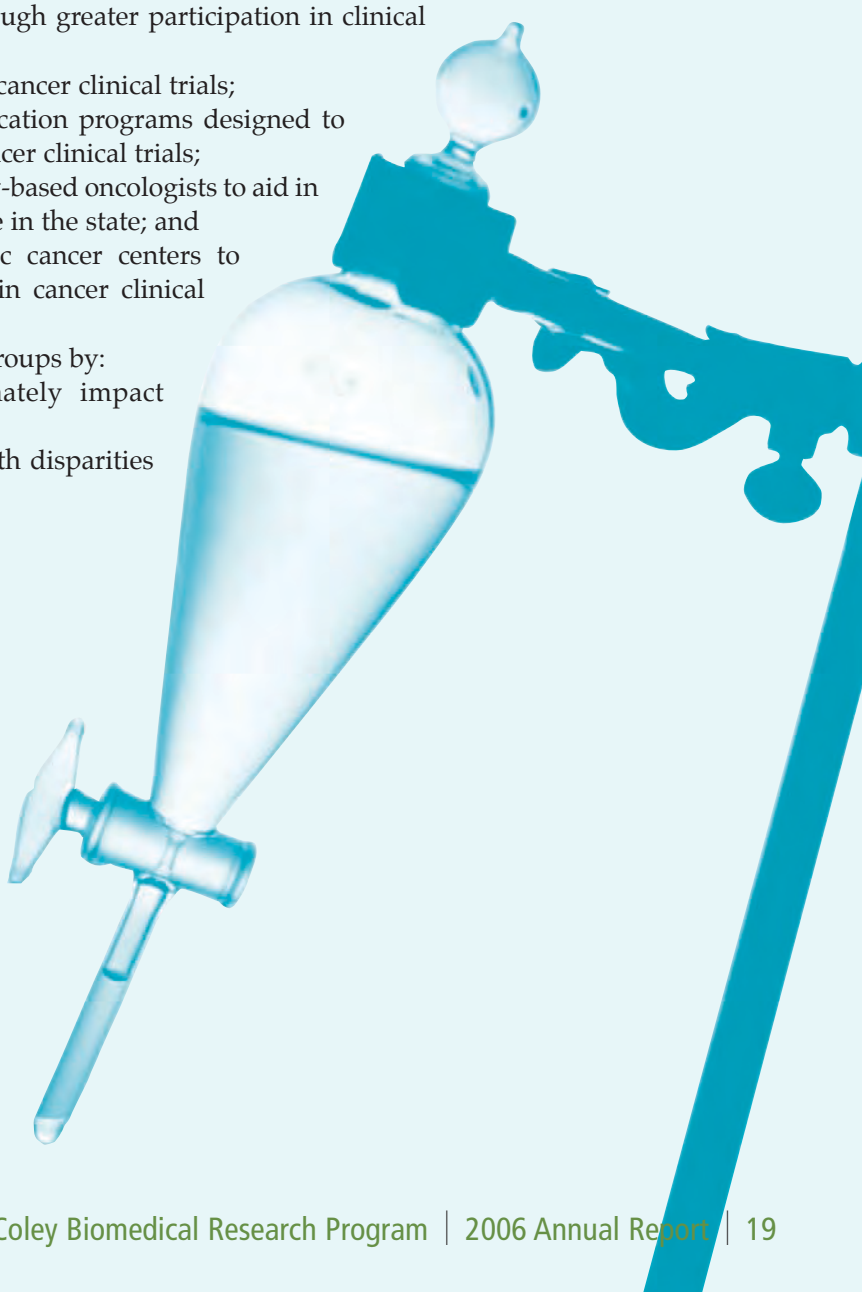
The council, which shall work in concert with the Florida Center for Universal Research to Eradicate Disease to ensure that the goals of the center are advanced, shall endeavor to dramatically improve cancer research and treatment in this state through:

(1) Efforts to significantly expand cancer research capacity in the state by:
   (a) Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state;
   (b) Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
   (c) Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
   (d) Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;
   (e) Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
   (f) Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research.

(2) Efforts to improve both research and treatment through greater participation in clinical trials networks by:
   (a) Identifying ways to increase adult enrollment in cancer clinical trials;
   (b) Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
   (c) Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and
   (d) Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks.

(3) Efforts to reduce the impact of cancer on disparate groups by:
   (a) Identifying those cancers that disproportionately impact certain demographic groups; and
   (b) Building collaborations designed to reduce health disparities as they relate to cancer.

History.—s. 11, ch. 2004-2; s. 7, ch. 2006-182.



Appendix C. Section 215.5602, *Florida Statutes* — James & Esther King Biomedical Research Program

1) There is established within the Department of Health the James and Esther King Biomedical Research Program funded by the proceeds of the Lawton Chiles Endowment Fund pursuant to s. 215.5601. The purpose of the James and Esther King Biomedical Research Program is to provide an annual and perpetual source of funding in order to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease. The long-term goals of the program are to:
   (a) Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease.
   (b) Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.
   (c) Improve the quality of the state's academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers.
   (d) Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional funding from outside the state.
   (e) Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

(2) Funds appropriated for the James and Esther King Biomedical Research Program shall be used exclusively for the award of grants and fellowships as established in this section; for research relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease; and for expenses incurred in the administration of this section. Priority shall be granted to research designed to prevent or cure disease.

(3) There is created within the Department of Health the Biomedical Research Advisory Council.
   (a) The council shall consist of 11 members, including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief executive officer of the Florida/Puerto Rico Affiliate of the American Heart Association, or a designee; and the chief executive officer of the American Lung Association of Florida, or a designee. The remaining 8 members of the council shall be appointed as follows:
      1. The Governor shall appoint four members, two members with expertise in the field of biomedical research, one member from a research university in the state, and one member representing the general population of the state.
      2. The President of the Senate shall appoint two members, one member with expertise in the field of behavioral or social research and one representative from a cancer program approved by the American College of Surgeons.
      3. The Speaker of the House of Representatives shall appoint two members, one member from a professional medical organization and one representative from a cancer program approved by the American College of Surgeons.

      In making these appointments, the Governor, the President of the Senate, and the Speaker of the House of Representatives shall select primarily, but not exclusively, Floridians with biomedical and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease. The appointments shall be for a 3-year term and shall reflect the diversity of the state's population. An appointed member may not serve more than two consecutive terms.
   (b) The council shall adopt internal organizational procedures as necessary for its efficient organization.
   (c) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the council in carrying out its responsibilities.
   (d) Members of the council shall serve without compensation, but may receive reimbursement as provided in s. 112.061 for travel and other necessary expenses incurred in the performance of their official duties.

(4) The council shall advise the Secretary of Health as to the direction and scope of the biomedical research program. The responsibilities of the council may include, but are not limited to:
   (a) Providing advice on program priorities and emphases.
   (b) Providing advice on the overall program budget.
   (c) Participating in periodic program evaluation.
   (d) Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the program.
   (e) Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials.
   (f) Developing criteria and standards for the award of research grants.

(g) Developing administrative procedures relating to solicitation, review, and award of research grants and fellowships, to ensure an impartial, high-quality peer review system.
(h) Developing and supervising research peer review panels.
(i) Reviewing reports of peer review panels and making recommendations for research grants and fellowships.
(j) Developing and providing oversight regarding mechanisms for the dissemination of research results.

(5) (a) Applications for biomedical research funding under the program may be submitted from any university or established research institute in the state. All qualified investigators in the state, regardless of institution affiliation, shall have equal access and opportunity to compete for the research funding.
(b) Grants and fellowships shall be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific merit, as determined by an open competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:
1. Investigator-initiated research grants.
2. Institutional research grants.
3. Predoctoral and postdoctoral research fellowships.

(6) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the Secretary of Health, in consultation with the council, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its scientific priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.

(7) The council and the peer review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest. A member of the council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee, or with which the member has entered into a contractual arrangement. Meetings of the council and the peer review panels shall be subject to the provisions of chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

(8) The department may contract on a competitive-bid basis with an appropriate entity to administer the program. Administrative expenses may not exceed 15 percent of the total funds available to the program in any given year.

(9) The department, after consultation with the council, may adopt rules as necessary to implement this section.

(10) The council shall submit an annual progress report on the state of biomedical research in this state to the Florida Center for Universal Research to Eradicate Disease and to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by February 1. The report must include:
(a) A list of research projects supported by grants or fellowships awarded under the program.
(b) A list of recipients of program grants or fellowships.
(c) A list of publications in peer reviewed journals involving research supported by grants or fellowships awarded under the program.
(d) The total amount of biomedical research funding currently flowing into the state.
(e) New grants for biomedical research which were funded based on research supported by grants or fellowships awarded under the program.
(f) Progress in the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

(11) The council shall award grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created in s. 381.922.

(12) Beginning in fiscal year 2006-2007, the sum of $6 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for purposes of the James and Esther King Biomedical Research Program pursuant to this section. From these funds up to $250,000 shall be available for the operating costs of the Florida Center for Universal Research to Eradicate Disease.

(13) By June 1, 2009, the Division of Statutory Revision of the Office of Legislative Services shall certify to the President of the Senate and the Speaker of the House of Representatives the language and statutory citation of this section, which is scheduled to expire January 1, 2011.

(14) The Legislature shall review the performance, the outcomes, and the financial management of the James and Esther King Biomedical Research Program during the 2010 Regular Session of the Legislature and shall determine the most appropriate funding source and means of funding the program based on its review.

(15) This section expires January 1, 2011, unless reviewed and reenacted by the Legislature before that date.

History.—s. 2, ch. 99-167; s. 4, ch. 2000-159; s. 2, ch. 2000-255; s. 5, ch. 2000-367; s. 4, ch. 2001-73; s. 1, ch. 2003-414; s. 8, ch. 2004-2; s. 3, ch. 2006-6-182.

Endnotes

[1] American Cancer Society, Cancer Facts and Figures 2006, http://www.cancer.org/docroot/STT/content/STT_1x_Cancer_Facts__Figures_2006.asp, accessed September 14, 2006, pp 5-6.

[2] Cancer Research and Treatment, American Cancer Society, Florida Division Position Statement for the 2006 Legislative Session, http://www.cancer.org/docroot/COM/content/div_FL/COM_4_5x_Cancer_Research_and_Treatment.asp?sitearea=COM, accessed September 14, 2006.

[3] National Cancer Institute, 2005 Fact Book, U.S. Department of Health and Human Services, Bethesda, MD, http://fmb.cancer.gov/financial/FY-2005-FACT-BOOK-FINAL.pdf, accessed September 15, 2006, p 66.

[4] Ibid, p.62.

[5] Ibid, p. 59.

[6] Statement on Fiscal Year 2007 Budget Request, Testimony delivered Apr. 6, 2006, before the U.S. House Subcommittee on Labor-HHS-Education Appropriations, to discuss the NCI budget request for Fiscal Year 2007, http://www.cancer.gov/aboutnci/FY07-budget-request, accessed September 14, 2006.

[7] Florida House Bill 1027, as Enrolled, http://www.myfloridahouse.gov/Sections/Documents/loaddoc.aspx?FileName=_h1027er.doc&DocumentType=Bill&BillNumber=1027&Session=2006, accessed September 20, 2006.

[8] Specialized Programs of Research Excellence (SPOREs) in Human Cancer for the Year 2007 (P50), http://grants1.nih.gov/grants/guide/pa-files/PAR-06-505.html, accessed September 28, 2006.

[9] s. 381.922, *(F.S.)*, paragraph (5).

[10] Ibid, paragraph (4).

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