

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 7061 PCB HCC 08-17 Biomedical Research
SPONSOR(S): Healthcare Council; Bean
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
Orig. Comm.: Healthcare Council	15 Y, 0 N	Quinn-Gato/ Massengale	Gormley
1) Policy & Budget Council		Leznoff	Hansen
2)			
3)			
4)			
5)			

SUMMARY ANALYSIS

This bill amends the James and Esther King Biomedical Research Program to consolidate processes for awarding funds appropriated by the Legislature for biomedical research. To accomplish this purpose, the bill revises provisions relating to funding and broadens the long-term goals of the program. The bill also renames the Biomedical Research Advisory Council the Biomedical Research Commission and increases the membership of the Commission from 11 to 15 members. The bill requires the establishment of certain committees, revises certain duties of the Commission, and implements new funding priorities for consideration by the Commission. The bill deletes requirements for other entities to establish and implement grant funding programs, and eliminates certain designated funding to entities for research activities. With the exception of the Bankhead-Coley Program, the bill requires that all biomedical research funding be consolidated under the James and Esther King Biomedical Research Program beginning in FY 2009-2010, and that the program serve as the exclusive source of funding biomedical research using state appropriated funds. The bill extends the sunset date of the James and Esther King Biomedical Research Program from January 1, 2011 to January 1, 2016.

The bill repeals statutes relating to Biomedical and Social Research, the Cervical Cancer Elimination Task Force, the Florida Cancer Council, the Florida Cancer Council mission and duties, the Florida Public Health Foundation, Inc., functions related to health awareness campaigns, the Alzheimer's Disease Advisory Committee, and cancer control and research and the Cancer Control and Research Commission.

The bill consolidates all biomedical research funding beginning Fiscal Year 2009-2010 into the Biomedical Research Trust Fund within the Department of Health, and extends the timeframe that funds may be carried forward from 3 to 5 years from the date of the original appropriation. Additionally, the bill reduces the recurring General Revenue appropriation to the Johnnie B. Byrd, Sr., Alzheimer's Disease and Research Institute by \$8.5 million in fiscal year 2008-2009 (See fiscal analysis).

Finally, the bill deletes cross references and other provisions to conform to the changes provided for in the bill.

The effective date of the bill is July 1, 2008.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government – The bill consolidates biomedical research under a single entity, the James and Esther King Biomedical Research Program. The bill deletes similar or redundant functions for facilitating or providing state funding for biomedical research.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida Programs or Entities Dedicated to Biomedical Research-Related Activities

Florida Statutes define at least 21 entities that are authorized to conduct research in this state using state appropriated funds.¹ There are another six entities that are statutorily authorized to make or recommend the award of biomedical research grants,² and another 12 statutory entities are authorized to facilitate biomedical research in this state through fostering coordination among research entities, recommending new areas of research focus, notifying researchers of grant opportunities in this state, hosting research summits, reviewing proposed research, collecting tissue for research or other similar activities.³

In several of these cases, the legislation provides for annual allocations of state general revenue funds to be used for developing research capabilities or awarding research grants.⁴ For example, the James and Esther King Biomedical Research Program receives an annual \$6 million appropriation plus additional designated annual funding from the Lawton Chiles Endowment Program, which totaled 3.9 million for fiscal year 2007-2008. The William G. Bankhead and David Coley Cancer Research Program receives an annual appropriation of \$9 million, and the Johnny B. Byrd, Sr. Alzheimer's Institute receives an annual appropriation of \$13.5 million.⁵

Additional funds for research may be allocated through the General Appropriations Act or raised by other means. In fact, for Fiscal Year 2007-2008, \$49.3 million was appropriated for the 21 entities

¹ See ss. 430.501-430.504 (Alzheimer's Disease Brain Bank); 430.502 (15 Alzheimer's Memory disorder clinics, only 13 of which currently receive state funds); s. 381.79 (Brain and Spinal Cord injury Research Programs); s. 1011.52 (First Accredited Medical School-University of Miami, which received an additional \$1.8 million in fiscal year 2007-2008 for cancer research); s. 381.853 (Florida Center for Brain Tumor Research); 1004.43, 210.20, and 210.201 (H. Lee Moffitt Cancer Center and Research Institute, Inc.); and 1004.445 (Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute).

² See ss. 215.5602 (James and Esther King Biomedical Research Program); 381.853 (Florida Center for Brain Tumor Research); 381.92 (Florida Cancer Council); 381.922 (William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program); 1004.445 (Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute); and 1004.435, F.S. (Cancer Control and Research Advisory Council).

³ See ss. 318.85 (Florida Biomedical and Social Research); 381.0404 (Center for Health Technologies); 1004.226 (The 21st Century Technology, Research, and Scholarship Enhancement Act); and 381.98, F.S. (Florida Public Health Foundation, Inc.); 385.202 (Statewide Cancer Registry Program); (Alzheimer's Disease Advisory Committee); 381.855 (Florida Center for Universal Research to Eradicate Disease); Florida Center for Brain Tumor Research; Institutional Review Board; s. 215.5601 (Lawton Chiles Endowment Fund); Cancer Control and Research Advisory Council; and (Florida Cancer Council).

⁴ See, e.g., s. 215.5602(12), F.S. (annually appropriating \$6 million in General Revenue to the Biomedical Research Trust Fund for the James and Esther King Biomedical Research Program).

⁵ See ss. 215.5602(12) (James and Esther King Biomedical Research Program); 381.922(5) (William G. "Bill" Bankhead, Jr., and David Coley Cancer research Program); and 1004.445(12), F.S. (Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute).

conducting research; \$32.4 million was appropriated for the 6 entities administering grant programs for research; and \$95⁶ million was appropriated for the 12 entities facilitating research.

Although connected by a common theme and purpose, these various programs operate independently, sometimes redundantly, to focus on selected diseases, narrowly defined objectives, and single-purpose initiatives, which may result in duplication of administrative costs or overlooking research on non-specified diseases.

Statutory Biomedical Research, Grant Award and Research Facilitation Programs in Florida

Brain and Spinal Cord Injury Trust Fund

Pursuant to s. 381.79, F.S., the Colleges of Medicine at University of Florida and University of Miami receive five percent of the monthly revenues, up to \$500,000 each, deposited into the Brain and Spinal Cord Injury Trust Fund pursuant to s. 318.21(2)(d), F.S., for their respective brain and spinal cord injury programs. The trust fund is funded a percentage of the fees (8.2%) generated from certain civil penalties paid to county courts, such as traffic-related fines, surcharges for boating or driving under the influence convictions, temporary license tag fees, and a percentage of the funds from the motorcycle specialty tag. For fiscal year 2007-2008, the University of Florida College of Medicine received \$500,000 and the University of Miami College of Medicine received \$1.2 million (\$500,000 as set forth above and an additional \$700,000) for their brain and spinal cord injury programs.

Florida Center for Brain Tumor Research

The Florida Center for Brain Tumor Research is located within the Evelyn F. and William L. McKnight Brain Institute at the University of Florida and guided by an 11-member Scientific Research Advisory Council.⁷ The Center coordinates with state public and private universities and hospitals to discover brain tumor cures and treatment modalities, monitors brain tumor research programs in the state, and is authorized by statute to develop a competitive, peer-review process for awarding brain tumor research. For fiscal year 2007-2008, the Center received \$250,000 non-recurring General Revenue for the purpose of conducting substance abuse treatment research.

The Florida Center for Universal Research to Eradicate Disease

Located in the Department of Health and guided by a 16-member advisory council, the Florida Center for Universal Research to Eradicate Disease ("FL CURED") was created to facilitate research to find cures for diseases such as cancer, heart disease, lung disease, diabetes, autoimmune disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease. To that end, the FL CURED is tasked with monitoring, coordinating, improving, and expanding all biomedical research programs in the state, facilitating funding opportunities by serving as a registry of all known grants opportunities in the state, assisting entities in preparing grant applications, developing and maintaining a registry of all known research, hosting an annual biomedical research summit, encouraging clinical trials by facilitating partnerships between researchers, treating physicians, and community hospitals, as well as partnerships between researchers in this state with institutions in other states.

Furthermore, the FL CURED hosts a website with links to peer-reviewed biomedical research which serves as a registry of all known opportunities for biomedical research grants, monitors supply and demand needs of researchers related to stem cell and other types of human tissue research, and facilitates partnerships among researchers working to cure all types of diseases.

⁶ The \$95 million includes the \$93.5 million appropriated pursuant to the 21st Century Technology, Research, and Scholarship Enhancement Act, s. 1004.226. The amount of the \$93.5 million that may be expended on biomedical research pursuant to these programs is indeterminate at this time.

⁷ s. 381.853, F.S.

The FL CURED receives an annual appropriation of \$250,000 from the James and Esther King Biomedical Research Program pursuant to s. 215.5602(12), F.S.

Prostate Cancer Awareness Program

Pursuant to s. 381.911, F.S., the Department of Health administers the Prostate Cancer Awareness Program in coordination with the Florida Public Health Foundation, Inc. The program, which is advised and assisted by a nine-member advisory council, was created to implement the recommendations of January 2000 of the Florida Prostate Cancer Task Force to provide for statewide outreach and health education activities related to early detection and awareness of prostate cancer.

Alzheimer's Disease Advisory Committee

Created pursuant to the Alzheimer's Disease Initiative, the Alzheimer's Disease Advisory Committee is comprised of 10 members appointed by the Governor, with the Secretary of the Florida Department of Elderly Affairs serving as an ex officio member.⁸ The Committee is tasked with advising the Department of Elderly Affairs about legislative, programmatic, and administrative matters that relate to Alzheimer's disease patients and their caretakers, including the development of fee schedules for functionally impaired elderly individuals, and evaluates the need for additional memory disorder clinics in the state.⁹ Further the Committee is authorized to advise the Department on the award of research grants related to Alzheimer's disease control or prevention, education, and training if funds are made available to the Department.¹⁰ Information obtained or retained by the Committee about clients received through files, reports, inspections, or otherwise, is confidential and exempt under Florida public records laws.¹¹

The Committee receives per diem and reimbursement for travel. For Fiscal Year 2006-2006, the total amount provided for per diem and travel for the Committee was \$7,599.39. The amount for Fiscal Year 2007-2008 cannot yet be determined.

Cancer Control and Research Advisory Council

The Cancer Control and Research Advisory Council is located within the H. Lee Moffitt Cancer Center and Research Institute and is comprised of 32 members appointed by the Governor and one member of the House of Representatives and the Senate appointed by the Speaker and President respectively.¹² The primary functions of the Council are to create the "Florida Cancer Plan," formulate and recommend to the State Surgeon General a plan for the care and treatment of persons suffering from cancer, and recommend the establishment of standard requirements for the organization, equipment, and conduct of cancer units or departments in hospitals and clinics in Florida.¹³

For example, if funds are specifically appropriated to the Council to develop or purchase standardized written summaries informing actual and high-risk breast cancer patients, prostate cancer patients, and men who are considering prostate cancer screening about treatment alternatives and the risks associated with that treatment.¹⁴ Such pamphlets are specifically referenced in ss. 458.324 and 459.0125, F.S., relating to breast cancer information and treatment alternatives that licensed physicians are required to provide patients.

⁸ s. 430.501, F.S.

⁹ Id.

¹⁰ s. 430.501, F.S.

¹¹ s. 430.504, F.S.

¹² s. 1004.435, F.S.

¹³ Id.

¹⁴ s. 1004.445(m), F.S.

Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute

The Legislature created the Alzheimer's Center and Research Institute at the University of South Florida in 2002, and subsequently renamed it the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute in 2004.¹⁵ The Legislature established the center as a not-for-profit corporation, and authorized the center to create both not-for-profit or for-profit corporate subsidiaries to fulfill its mission.¹⁶

Grants are awarded by the center's board of directors for the purpose of conducting Alzheimer's disease research, following a review of all research proposals by a peer review panel of independent, scientifically qualified individuals.¹⁷

During 2007 Special Session C, the Legislature appropriated \$13.5 million in recurring general revenue funding to the Grants and Donations Trust Fund within the Department of Elderly Affairs (DOEA) for use by the Center.¹⁸ The funding provided to the center is intended to assist the center in its efforts in researching, educating, treating, preventing, and detecting Alzheimer's disease, as well as "providing institutional research grants and investigator-initiated research grants, developing and operating integrated data projects, and providing assistance to statutorily-designated memory disorder clinics as provided under s. 430.502, F.S." From this annual appropriation, not less than 80 percent of the funds are to be expended for these statutorily-prescribed purposes, and not less than 20 percent are to be expended in awarding peer-reviewed investigator-initiated research grants.¹⁹

Section 1004.445, F.S., expires on January 1, 2011, unless reviewed and reenacted by the Legislature before that date.²⁰

Center for Health Technologies

Pursuant to s. 381.0404, F.S., the Center for Health Technologies is required to be administered by a statutory teaching hospital in Miami-Dade County. When it was active, the Mount Sinai Medical Center administered the program. The Center, which received federal funding, functioned to encourage the development and growth of health sciences in the state, with an emphasis on technologies which will help to prevent illness and reduce health care costs; assist coordination between and with educational institutions, health care providers, and persons engaged in research and development of health care products; provide services to persons and incipient firms engaged in the incubation of health care products; assist in technology transfer; and establish academic laboratories, libraries, and other resource facilities to be shared among the Center's constituents. The Center is not currently active at this time.

Biomedical and Social Research Review Council

The Biomedical and Social Research Review Council was created in the Department of Health and was comprised of 3 members appointed by the Governor (1), Speaker (1), and the Senate President (1).²¹ The purpose of the Council was to evaluate proposed biomedical research to be conducted on adults or children in the state of Florida by the Department of Health or with funds appropriated to the Department of Health. The Council is no longer functional as the Institutional Review Board within the Department of Health was created pursuant to s. 381.86, F.S., in 2004 to review all biomedical or behavioral research on human subjects that is funded or supported by the Department of Health.²²

¹⁵ Chapters 2002-387 and 2002-289, Laws of Florida (L.O.F.), and Chapter 2004-2, L.O.F.

¹⁶ s. 1004.445(2), F.S.

¹⁷ s. 1004.445(8), F.S.

¹⁸ Chapter 2007-332, L.O.F.

¹⁹ Id.

²⁰ s. 1004.445(15), F.S.

²¹ s. 381.85, F.S.

²² See 2004-350, L.O.F.

Cervical Cancer Elimination Task Force

The Cervical Elimination Task Force was established in 2004 pursuant to s. 381.912, F.S., to recommend actions and strategies to reduce costs and burdens associated with cervical cancer in Florida. The 11-member Task Force is tasked with presenting interim reports by set deadlines to the Speaker, Governor, Senate President, the FL CURED, the Florida Cancer Council, and the Florida Public Health Foundation, Inc., with the final report scheduled for delivery by June 30, 2008. The Task Force is statutorily sunset after the delivery of that final report.

Florida Cancer Council

The Florida Cancer Council is an 18-member Council located in the Department of Health.²³ The Council coordinates with the FL CURED and identifies ways to attract new research talent in the state, seeks to continue to improve research and treatment by identifying ways to increase enrollment in clinical trials, creates awareness within the medical professional industry of clinical trials available in the state, aids other multidisciplinary research-supported activities as they inure to the advancement of cancer research, ensures improved cancer research and treatment, and seeks to make Florida a center of excellence for cancer research.²⁴

The Council is statutorily authorized to institute a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research in the state, and consult with the FL CURED in making annual funding recommendations to the Legislature and Governor. At present, the Council is not active.

Florida Public Health Foundation, Inc.

The Florida Public Health Foundation, Inc. is a 501(c)(3) corporation managed by an executive director appointed by the Board of Directors.²⁵ The Foundation enters into contract with the Department of Health for services related to disseminating information regarding biomedical research and clinical trials in the state, making treatment providers and patients aware of specified diseases, conditions, and available methods of preventing, diagnosing, treating, and curing those diseases and conditions, and protecting and improve the health and well-being of Floridians through partnerships committed to program innovation, education, applied research, and policy development.²⁶

The Foundation has a monthly health awareness schedule and it coordinates with the FL CURED and the Department of health to ensure communication with biomedical researchers and health care providers according to the monthly schedule.²⁷ The Foundation and the Department of Health are statutorily authorized to enter into partnerships with providers of continuing education to ensure that practitioners are aware of the most recent and complete diagnostic and treatment tools.²⁸

As of December 7, 2007, the Department of Health had contracted with the Foundation for \$10,550 in services for the current fiscal year.

²³ s. 381.92, F.S.

²⁴ s. 381.921, F.S.

²⁵ s. 381.98, F.S.

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.*

Examples of Current Grant Award Programs

The following are examples of award processes used by current state and federal grant award programs.²⁹

The James and Esther King Biomedical Research Program

Pursuant to s. 215.5602, F.S., the James and Esther King Biomedical Research Program, administered by the Department of Health, recommends the award of grants for biomedical research concerning tobacco related diseases.

To award grants, the Department of Health, in coordination with the James and Esther King Program, issues a call for grant applications. Any university or established research institute in the state is eligible to compete for funding through the program, and the program awards investigator-initiated research grants, institutional research grants, and predoctoral and postdoctoral research fellowships.³⁰

Interested applicants submit their applications electronically to the Lytmus Group, a Department of Health contractor that facilitates the independent, peer-review and scoring of applications by disinterested peer reviewers outside the state of Florida. The Lytmus Group has approximately 150 peer reviewers that are available to review and score applications, and traditionally has assigned 5 reviewers per application.³¹ After peer-reviewers review the assigned application, the application receives a score of one through five from each reviewer, with one being the best score and five being the worst. Traditionally, Lytmus would eliminate the highest and lowest scores and average the remaining three scores to come up with an overall score for the application.³²

Once the average score for applications is derived, the Lytmus Group removes all identifying information about the applicants and submits a ranking report to the Biomedical Research Advisory Council ("BRAC"). The BRAC is comprised of 11 members including the chief executive officer of the Florida Division of the American Cancer Society, the chief executive officer of the Greater Southeast Florida/Puerto Rico Affiliate of the American Heart Association, and the chief executive officer of the American Lung Association of Florida, or their designees, as well as 8 individuals appointed by the Governor (4), Speaker (2) and Senate President (2). In an open meeting, the BRAC discusses the ranking report from the peer reviewers and develops funding priorities. Included in those funding priorities is a score break-off point, meaning the BRAC will not consider applications that receive an average score below a certain level. Moreover, the BRAC considers potential funding and the scientific merit, including its relatedness to tobacco-related diseases, for each application up for consideration. The BRAC then recommends to the State Surgeon General the amount and length of funding for each successful application.

Department of Health staff conducts a final review of the applications for eligibility and the State Surgeon General makes a final funding decision based, which may include different award amounts than those recommended by the BRAC. After funds are appropriated by the Legislature, the DOH issues award letters, and enters into contracts with successful grantees in the beginning of the new fiscal year. Grant awards run from 1-3 years depending upon the grant type.

If an award is for more than one year, then before funding is continued for each successive year, the grantee's progress must be re-evaluated, often by the peer reviewers initially assigned to the application, to determine whether funding should be continued.

²⁹ Of these examples, only the James and Esther King Program and Bankhead-Coley Program award process are affected by this bill. The bill does not repeal or modify in any way, the Department of State Historical Preservation Grant Program.

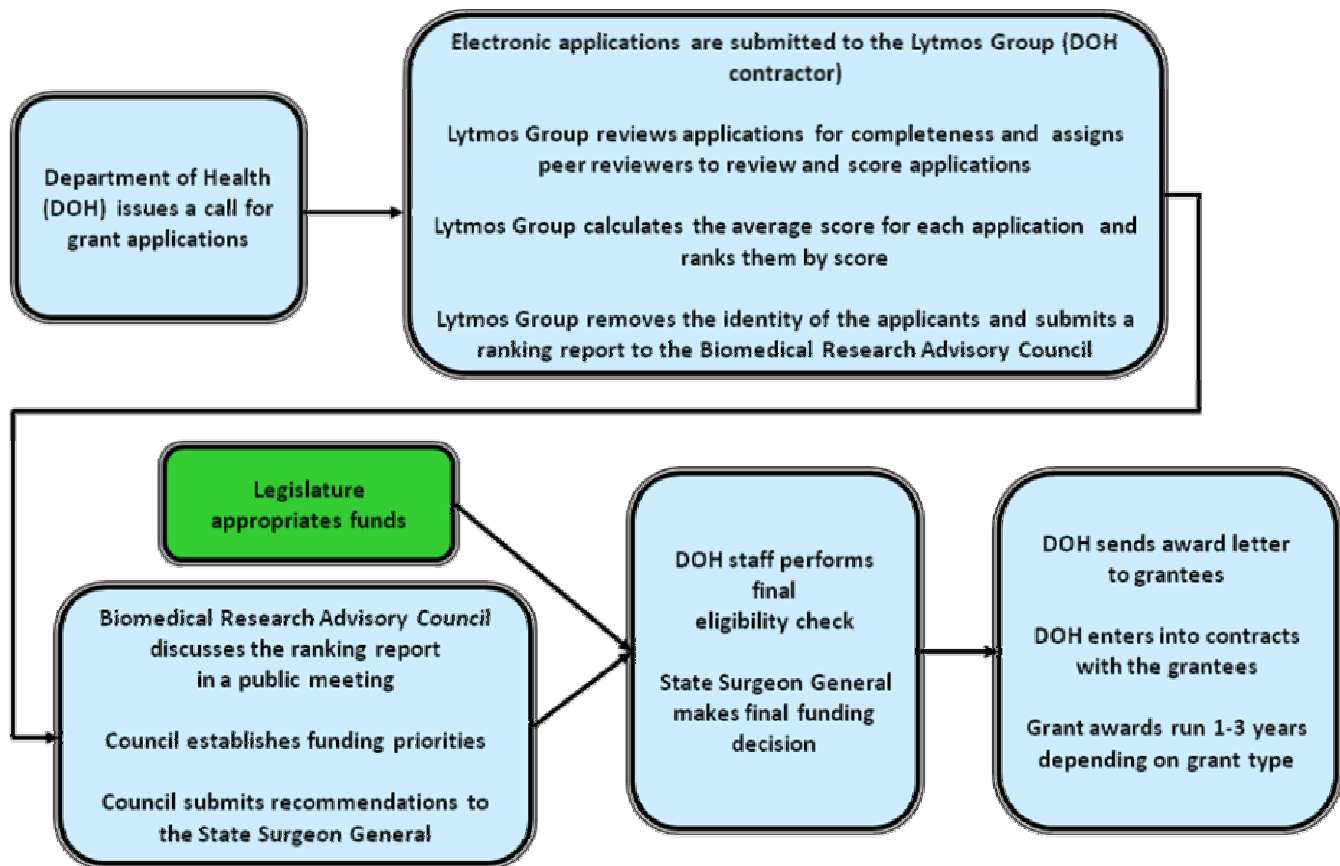
³⁰ s. 215.5602, F.S.

³¹ As set forth in more detail below, the BRAC traditionally assigned 5 reviewers per application; however, for this FY, the BRAC will be piloting new methods of reviewing and scoring by peer reviewers.

³² This year, the BRAC has been piloting a new process for determining the average score for each application; however, this analysis will focus on the traditional model that the BRAC has used in the past.

The above-described process for awarding grants and fellowships by the James and Esther King Program is illustrated in the following flow chart:

JAMES AND ESTHER KING BIOMEDICAL RESEARCH PROGRAM GRANT AWARD PROCESS



The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program

Pursuant to s. 381.922, F.S., the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program ("Bankhead-Coley Program") is also located in the Department of Health and administered by the Department and guided by the Biomedical Research Advisory Council. The purpose of the Bankhead-Coley Program is to provide funding for grants that further the search for cures of cancer.

The Bankhead-Coley Program utilizes identical processes as the James and Esther King Program for awarding grants to any university or established research institute in the state for collaborative research projects, including those that advance the finding of cures through basic or applied research, investigator-initiated research, or institutional research.³³ (See James and Esther King Program description and flow chart above).

As set forth above, the Bankhead-Coley Program has been designated a \$9 million annual appropriation in General Revenue, which is appropriated to the Biomedical Research Trust Fund.³⁴ The Program is scheduled to sunset on January 1, 2011 unless reenacted by the Legislature by that date.³⁵

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

The National Institutes of Health Grant Award Programs

Similar to the James and Esther King Biomedical Research Program, the National Institutes of Health (“NIH”) traditional model³⁶ for awarding grants includes a two-step review process for each grant awarded by the more than 20 Centers and Institutes comprising the NIH.

In most cases, after grant announcements or requests for applications are made, all applications are sent to the NIH Center for Scientific Review where the applications are either assigned to a Scientific Review Group³⁷ or an Initial/Integrated Review Group, depending on whether the application has been assigned to a specific Institute or Center, for peer-review.³⁸ These review groups usually meet three times a year in closed meetings, and are comprised of members appointed by the NIH or a particular Institute/Center Director. Assignment to a particular review group is made based on the scientific or technical needs of the group.

Prior to peer-review meetings, peer reviewers prepare individual written critiques of the applications based upon criteria established by the NIH, which includes the significance, approach, and innovation of the proposed research, the qualifications and training of the researchers involved, and the conduciveness of the scientific environment within which the research will be conducted to producing successful research.³⁹ At the peer review meetings, reviewers openly discuss and critique the applications and, at the conclusion of the discussion, each peer reviewer scores the application. Each reviewer’s score is then averaged to create a “priority score” for the application.

Applications and scores are then referred to NIH program staff, and staff develops a grant funding plan for each application and submits the plan to the National Advisory Council or Board for the second level of review.

National Advisory Councils are established at each NIH Institute or Center, and are comprised of scientists focused in the areas of biomedical, behavioral, social and public health research, as well as leaders in fields such as economics, law, management, health policy and public policy. Patients, relatives of patients, and advocates may also serve on the council.⁴⁰ The Council is tasked with reviewing grant funding plans and considering the needs of the Institute or Center, and makes funding recommendations to the Director of the Institute or Center. Similar to the James and Esther King Biomedical Research Program, recommended funding is usually based upon anticipated funding levels, as annual appropriations bills may not have passed through Congress by the time these recommendations are made. The Institute or Center Director makes the final funding decision based upon Council and staff advice.

Before applications are funded, applications must go through a “Pre-Award Process,” which consists of review by NIH staff to: ensure alignment with the NIH’s funding principles; review the proposed budget for the project; assess the applicant’s management systems; ensure applicant eligibility; and ensure compliance with public policy requirements. At the conclusion of this process, a “Notice of Award” is issued to successful applicants, which includes all terms and conditions, including the length of the award, and contact information for the grants management officer assigned to the applicant by the Institute or Center. Awards range from 1-5 years; however, the grant period is initially 1 year, and

³⁶ While there are many new review processes being piloted by the NIH, this analysis will focus on the traditional grant award process used by the NIH. Except where expressly otherwise indicated, all information in this section has been derived from the “Grants” link on the NIH website located at <http://grants.nih.gov/grants/oeer.htm>, and this footnote shall serve as attribution for all such information.

³⁷ The Center for Scientific Review has approximately 18,000 experts available to review grant applications through Scientific Review Groups.

³⁸ Sometimes a particular grant announcement or application calls for reviewers to have particular expertise, or there are conflicts of interest that may exist, so the application will be assigned to a Special Emphasis Panel for the initial peer review; however

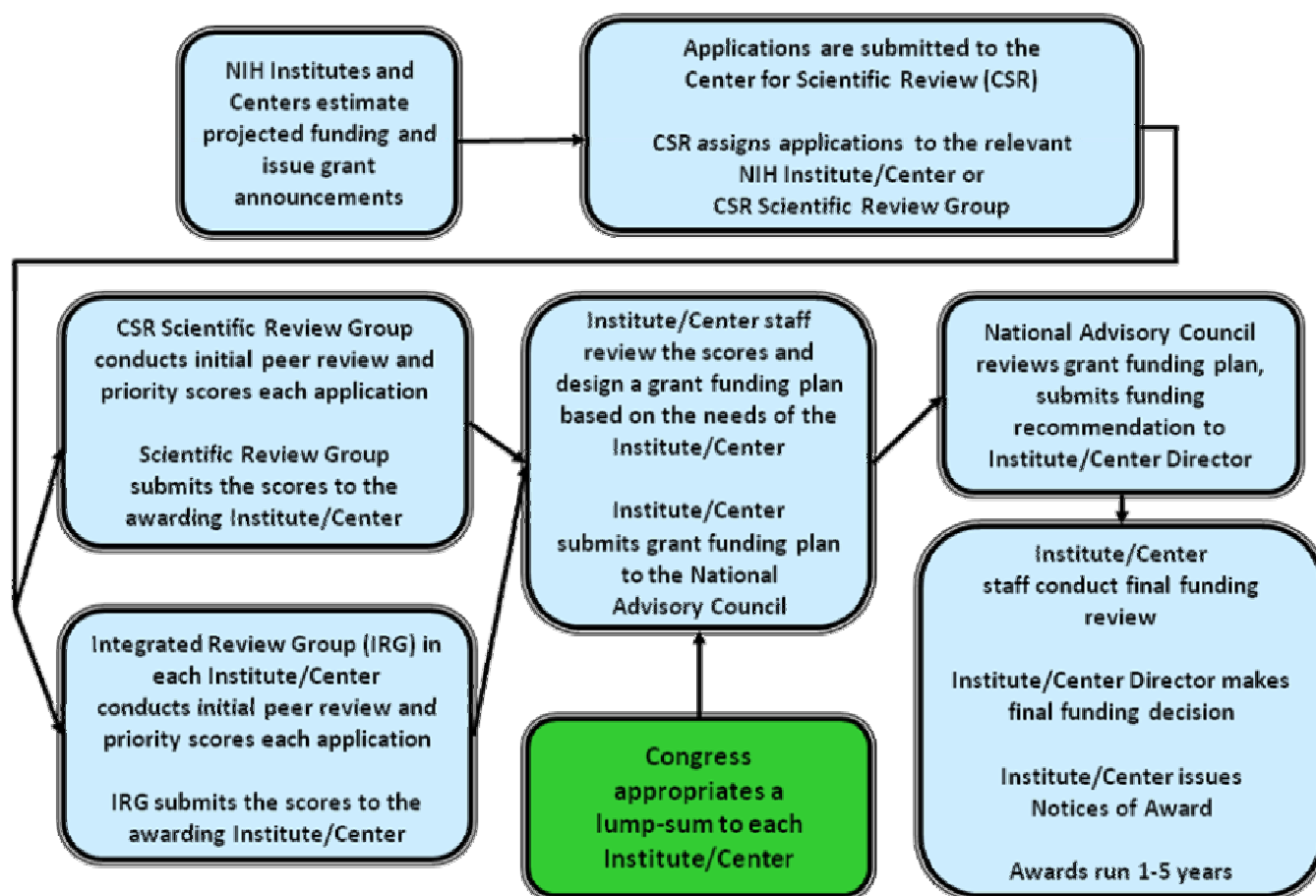
³⁹ Peer-reviewers will also consider public policy issues/factors in their review, such as policies concerning the protection of human subjects, use of vertebrate animals in research, the inclusion of women, minorities and children in research.

⁴⁰ Members of the National Advisory Councils are appointed by either the Secretary of Health or the President of the United States.

subsequent continuation awards are made in 1 year increments.⁴¹ Each year grantees must submit a “Non-Competing Grant Progress Report” application, and the NIH Institute or Center that made the award conducts an annual assessment of the grantee’s progress and management practices to determine whether to continue funding for the next year of the grant award period.⁴²

The National Institutes of Health grant award process described above is illustrated in the following flow chart:

NATIONAL INSTITUTES OF HEALTH GRANT AWARD PROCESS



The Department of State Historical Preservation Grant Program⁴³

The Florida Department of State, through its various divisions, administers several grant award programs, including the Florida Historic Preservation Grant Award Program (“Historic Grants Program”).⁴⁴ One of the grant types awarded by the Historic Grants Program are special category grants-in-aid, which are grants that range from \$50,000 to \$350,000⁴⁵, and are awarded to assist with

⁴¹ See 42 C.F.R. s. 52a.6(a)-(b).

⁴² *Id.*

⁴³ The information in this section of the analysis is comprised of information obtained from Florida Statutes (ss. 267.0612, 267.0617, F.S.) applicable Department of State Rules (s.1A-35.002 – 1A-35.007, F.A.C.) and from the Florida Department of State, Division of Historical Resources website (<http://www.flheritage.com>) pertaining to grant awards, including links to grant guidelines and overviews therein provided.

⁴⁴ This program is administered by the Division of Historical Resources within the Department of State. The Department of State also has grant award programs for libraries, museums, and other cultural affairs programs.

⁴⁵ A minimum need and match of \$50,000 is required.

major restorations and rehabilitations of historic buildings and structures, major archeological excavations, and major museum exhibits relating to Florida history.⁴⁶

The Florida Historical Commission⁴⁷ comprises 11 members, seven of whom are appointed by the governor and 4 of whom are appointed by the Speaker of the House and the Senate President (2 each), and advises and assists the Division in by reviewing and ranking special category grant applications and advises the Division with regard to policy and preservation needs of the State. The Department of State has developed extensive rules for administering the program, including application requirements and criteria and procedures for reviewing and evaluating applications.

To award special category grants, which are open to agencies or departments of the state, city, county, or unit of local government, and not-for-profit organizations, the Division of Historical Resources makes a grant announcement. Applications are sent the Division, where they are initially reviewed by Division staff to ensure completeness and eligibility. The Division provides that Commission with an opinion as to whether the applicant and project are eligible for the type of grant assistance indicated in the application, as well as any additional information or clarification requested from an applicant. Prior to being submitted to members of the Commission, the Division assigns each application an identifying number so that the identity of the applicant is not known to the Commission.

The Commission reviews and evaluates each application in an open meeting, and makes recommendations to the Secretary of State, including a priority ranking of each application that reflects those evaluations, funding levels for each application, and any appropriate special conditions for certain applications. The priority ranking is developed by ranking each project relative to the others.

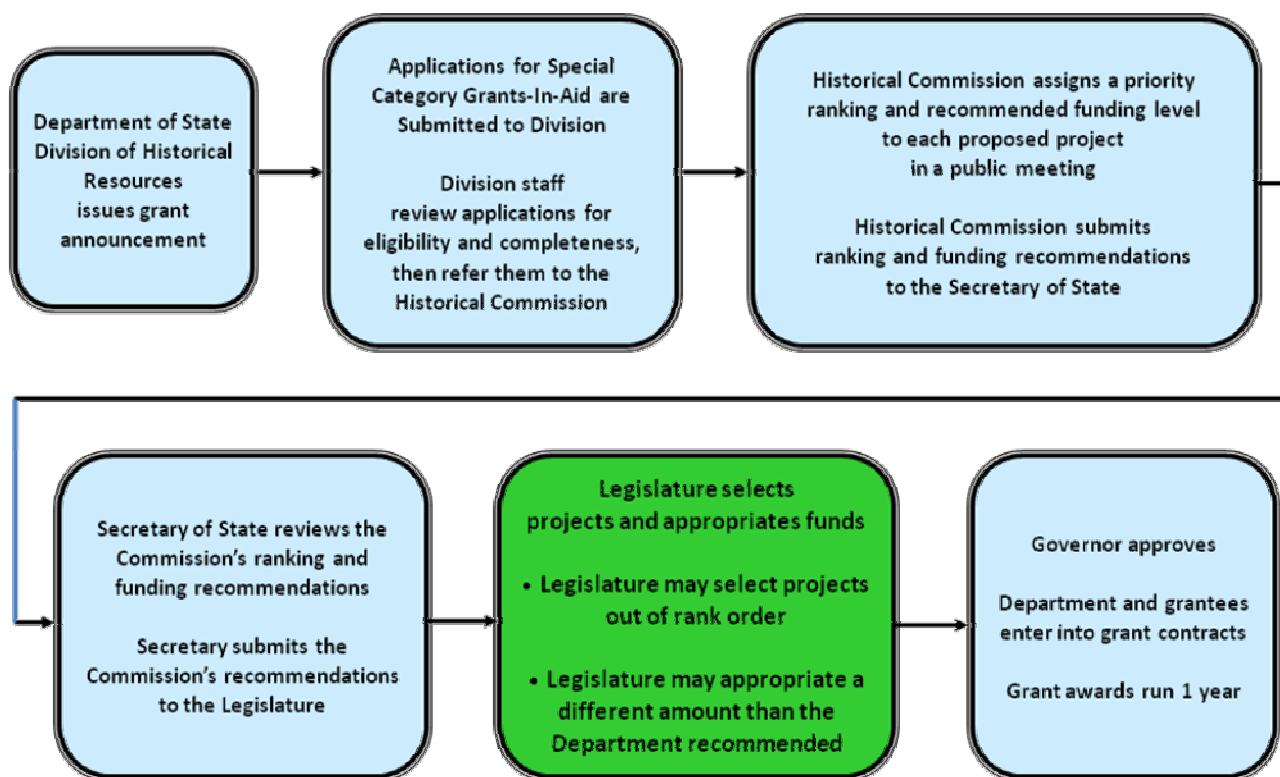
The Secretary of State reviews the Commission's priority ranking and funding recommendations and develops of final priority listing of the applications considered, as well as the recommended funding level for each, and submits the ranking to the Legislature for approval and funding. Once the Legislature makes a final funding decision and appropriates funds, the Division enters into grant award agreements with successful applicants. Funding is limited to projects that go through this review process.

The above-described process for awarding special category grants-in aid by the Department of State Historical Commission is illustrated in the following flow chart:

⁴⁶ The Historic Grants Program also awards historic preservation grant-in-aid, which are 1:1 matching grants up to \$50,000 awarded for excavating, identifying, protecting, and rehabilitating historic and archeological sites, providing public information about these important resources, and encouraging historic preservation in smaller cities; however, the grants are awarded through a somewhat different process from the process described herein and are not subject to Legislative approval for funding.

⁴⁷ The Commission, created in 2001 to assist the Division and enhance public participation and involvement in the process, replaced the Historic Preservation Advisory Council.

HISTORICAL PRESERVATION SPECIAL CATEGORY GRANTS-IN-AID AWARD PROCESS



Effect of Proposed Changes

The bill amends the James and Esther King Biomedical Research Program to consolidate processes for awarding funds appropriated by the Legislature for biomedical research beginning in 2009-2010. To accomplish this purpose, the bill revises provisions relating to funding and renames the Biomedical Research Advisory Council the Biomedical Research Commission (the "Commission") in order to incorporate the increased responsibilities of the Commission. The bill amends the membership of the Commission from 11 to 15 members, including the chief executive officer of the South Coastal Region of the American Diabetes Association and the president of the Florida Medical association, or their designees, and four representatives from volunteer health organizations operating in Florida that focus on Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or autoimmune or genetic disorders appointed by the Speaker of the House of Representatives (2 appointees, 1 of which is an additional appointment) and the President of the Senate (2 appointees, one of which is an additional appointment) as new members. In addition, the bill requires establishment of certain committees by the Commission.

The bill provides that, other than the Bankhead-Coley Program, the James and Esther King Program shall serve as the exclusive source of state funding for biomedical research. The bill exempts the World Class Scholars Program, the Centers of Excellence, or the State University Research Commercialization Assistance Grant Programs from these limitations on state funding. The bill deletes requirements for other entities to establish and implement grant funding programs and revises or repeals other sections of statute in order to conform to the consolidation of these activities under the James and Esther King Biomedical Research Program. Finally, the bill segregates the Biomedical Research Trust Fund to ensure that funds appropriated for the Bankhead-Coley Cancer Research Program and tobacco-related research through the James and Esther King Program are not co-mingled with funds appropriated for other biomedical research grants that will be awarded by the James and Esther King Program pursuant to the changes in the bill, and extends the amount of time that balances of appropriations from the Biomedical Research Trust Fund can be carried forward to five years.

Specifically, the bill:

- Expands the disease focus of the James and Esther King Biomedical Research Program to include the most deadly and widespread acute, chronic, and degenerative disease including, but not limited to tobacco-related diseases, cancer, cardiovascular disease, stroke, pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.
- Revises the long-term goals of the Program to incorporate the new expanded disease focus.
- Beginning in fiscal year 2009-2010, expands the types of research that qualify for grants and fellowships awarded by the Program to include the new disease focus of the Program.
- Renames the Biomedical Research Advisory Council the Biomedical Research Commission.
- Increases the membership of the Biomedical Research Commission from 11 to 15 members. The new specifically designated members include chief executive officer of the South Coastal Region of the American Diabetes Association and the president of the Florida Medical association, or their designees. In addition, the bill provides one additional appointment each for the President of the Senate and the Speaker of the House of Representatives consisting of a member from a volunteer health organization operating in Florida that focuses on Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or autoimmune and genetic disorders. Further the bill modifies one of the current appointees of the Speaker from one appointee representing a professional medical organization to one appointee from a volunteer health organization as described above and the Senate President from one appointee representing a cancer program approved by the American College of Surgeons to one appointee from a volunteer health organization as described above.
- Provides that, except for the Bankhead-Coley Cancer Research Program, in fiscal year 2009-2010, the James and Esther King Program shall serve as the exclusive source of awarding grants or fellowships for biomedical research in the state using state funds, and provides an exception for programs that award grants using non-state appropriated funds.
- Requires the Commission to create committees to focus on disease-specific areas and adopt policies and procedures regarding the creation and composition of the committees, reporting and recommendations by the committees to the Commission, coordination between the Commission and committees, and the methods for receiving information and recommendations from outside entities.
- Revises the advisory nature of the Biomedical Research Commission, authorizing the Commission to make recommendations to the State Surgeon General and Legislature for future appropriations.
- Starting in 2009, requires the Commission to provide to the State Surgeon General a priority list of biomedical research projects, including the recommended length and amount of funding, which shall be forwarded without modification to the Legislature for consideration.
- Expands the length of awards from 1-3 years to 1-5 years, and requires research to go through the Program award process in order to receive state funds.
- Requires any program, board, commission council, advisory group, or committee (other than the Bankhead-Coley Program, the World Class Scholars Program, the Centers of Excellence, or the State University Research Commercialization Assistance Grant Programs), created in state law that currently awards, intends to award, or recommends the award of, biomedical research grants, from state funds to apply for grants through the Program or make recommendations to the Biomedical Research Commission for Fiscal Year 2009-2010 and thereafter.
- Requires the Biomedical Research Commission to take several factors into consideration when prioritizing grant awards, specifically including applications that have the most profound impact on the most deadly and widespread diseases and applications propose the best and most efficient use of state funds.
- Reduces administrative expenses for the Program from 15 percent to ten percent beginning fiscal year 2009-2010.

- Consistent with the changes in the bill, provides an expiration date for the Commission's functions as they relate to the Bankhead-Coley Program.
- Modifies provisions related to appropriations to the James and Esther King Program to conform to the changes in the bill.
- Makes identical changes to the Bankhead-Coley Program within the Department of Health, directing the Biomedical Research Commission, starting in 2009, to provide the State Surgeon General a priority list of biomedical research projects for the Bankhead-Coley Program, including the recommended length and amount of funding, which shall be forwarded to the Legislature for consideration.
- Provides a sunset date for the Bankhead-Coley Program of June 30, 2009 and removes provisions related to sunset review.
- Provides for the expiration of dedicated funding from the Brain and Spinal Cord Injury Program Trust Fund to the University of Florida and University of Miami Medical Schools on June 30, 2009.
- Requires the Florida Center for Brain Tumor Research to compete for state research funds through the James and Esther King Program beginning in fiscal year 2009-2010.
- Expands the functions of the FL CURED to include attracting new research talent to the State, providing information regarding research needs of the state to the Biomedical Research Commission, and, upon a specific appropriation, disseminating information about specified diseases and conditions, and available methods of preventing, diagnosing, treating, and curing those diseases or conditions.
- Revises the make-up of the advisory council to the FL CURED to conform to changes in the bill.
- Requires the Department of Elderly Affairs to consult with the Alzheimer's Disease Brain Bank and model day care programs concerning the need for additional memory disorder clinics.
- Deletes cross references to the Florida Cancer Control and Research Advisory Council, and materials to be developed by the advisory council, in provisions concerning breast cancer treatment alternatives and information in order to conform to changes in the bill.
- Revises the duties of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, deleting the authority of the Center to provide research grants beginning in 2009-2010, requiring the Center to compete for state funds for research activities, and provides an expiration date of June 30, 2009 to the council of scientific advisors.
- Repeals the Center for Health Technologies, Biomedical and Social Research, the Cervical Cancer Elimination Task Force, the Florida Cancer Council, the Florida Cancer Council mission and duties, the Florida Public Health Foundation, Inc., Health awareness campaigns, the Alzheimer's Disease Advisory Committee, cancer control and research, and the Cancer Control and Research Advisory Council.

C. SECTION DIRECTORY:

Section 1. Amends s. 20.435, F.S., relating to the Biomedical Research Trust Fund.

Section 2. Amends s. 215.5602, F.S., relating to the James and Esther King Biomedical Research Program.

Section 3. Amends s. 381.79, F.S., relating to the Brian and Spinal Cord Injury Trust Fund.

Section 4. Amends s. 381.853, F.S., relating to the Florida Center for Brain Tumor Research.

Section 5. Amends s. 381.855, F.S., relating to the Florida Center for Universal Research to Eradicate Disease.

Section 6. Amends s. 381.911, F.S., relating to the Prostate Cancer Awareness Program.

Section 7. Amends s. 381.922, F.S., relating to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Council.

Section 8. Amends s. 430.502, F.S., relating to Alzheimer's disease; memory disorder clinics and day care and respite care programs.

Section 9. Amending s. 430.503, F.S., relating to Alzheimer's Disease Initiative; fees and administrative expenses.

Section 10. Amending s. 430.504, F.S., relating to Confidentiality of information related to Alzheimer's disease issues.

Section 11. Amending s. 458.324, F.S., relating to Breast Cancer; information on treatment alternatives.

Section 12. Amending s. 459.0125, F.S., relating to Breast cancer; information on treatment alternatives.

Section 13. Amends s. 1004.445, F.S., relating to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

Section 14. Repeals ss. 381.0404, 381.85, 381.912, 381.92, 381.921, 381.98, 381.981, 430.501, and 1004.435, F.S., relating to the Center for Health Technologies, Biomedical and Social Research, the Cervical Cancer Elimination Task Force, the Florida Cancer Council, the Florida Cancer Council mission and duties the Florida Public Health Foundation, Inc., Health awareness campaigns, the Alzheimer's Disease Advisory Committee, cancer control and research, and the Cancer Control and Research Advisory Council, respectively.

Section 15. Provides for severability if any provision of the act is held invalid.

Section 16. Provides an effective date of July 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Consolidation of process for awarding state funds for biomedical research will make it easier for researchers, including those in the private sector, to identify and apply for available funding. The amended process also allows researchers in a broader range of disease areas to compete for and obtain funding.

D. FISCAL COMMENTS:

The bill consolidates all biomedical research funding beginning Fiscal Year 2009-2010 into the Biomedical Research Trust Fund within the Department of Health. All funds deposited into the Biomedical Research Trust Fund must be used for the award of grants and fellowships related to the program for which funding is appropriated. The bill also extends the timeframe that funds may be carried forward from 3 to 5 years from the date of the original appropriation.

The statutorily required \$9 million annual General Revenue appropriation for the Bankhead-Coley Cancer Research Program remains the same until the program sunsets on June 30, 2011. Moreover, the statutory requirement to allocate \$6 million for the James and Esther King Biomedical Research Program, as well as dedicated funding to the Program from the Lawton Chiles Endowment Fund, remains intact. Additionally, the bill reduces appropriations to the Johnnie B. Byrd, Sr., Alzheimer's Disease and Research Institute to \$5 million beginning in Fiscal Year 2008-2009; and, beginning Fiscal Year 2009-2010 and each fiscal year thereafter, the bill limits the use of the Institute's funds to providing assistance to statutorily designated memory disorder clinics and for education, treatment, prevention and early detection of Alzheimer's disease, developing and operating integrated data projects, and providing assistance to statutorily designated memory disorder clinics. Finally, all entities, unless otherwise specified, who seek to conduct biomedical research using state funds, are required to apply for funding through the James and Esther King Program.

The bill specifies that the revenues in the Brain and Spinal Cord Injury Program Trust Fund appropriated to the University of Florida and the University of Miami for spinal cord injury and brain injury research sunsets June 30, 2009.

The 21st Century Technology, Research, and Scholarship Act is expressly exempted from the requirements of this act and, therefore, may continue to receive funding for biomedical-related research in the general appropriations act.

The bill clarifies that the 15 members of the Biomedical Research Commission may be reimbursed for travel and other necessary expenses when they attend committee meetings. The bill specifies that the department must submit an annual report by February 1, to the Legislature. The fiscal impacts for these two items are anticipated to be nominal.

Currently, the James and Esther King Biomedical Research Program is allowed to contract on a competitive-bid basis with an appropriate entity to administer the program. The contracted administrative expenses may not exceed 15 percent of the total funds available to the program in any given year. The bill reduces administrative expenses to 10 percent of the total funds effective July 1, 2009.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Department of Health has sufficient rulemaking authority to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

N/A

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 18, 2008, the Health Care Council adopted one amendment to the PCB, which reduces administrative expenses for the biomedical research program to five percent beginning July 1, 2011.

The PCB was reported favorably with one amendment.