A bill to be entitled

An act relating to biomedical research; amending s. 20.435, F.S.; revising funding sources for trust fund to conform to changes made by this act; providing for segregation of trust funds based on the type of research conducted; revising the time by which certain balances of appropriations from the Biomedical Research Trust Fund can be carried forward; amending s. 215.5602, F.S.; revising provisions related to the James and Esther King Biomedical Research Program; revising long-term program goals; revising provisions related to program funds and funding; renaming the Biomedical Research Advisory Council the Biomedical Research Commission; revising membership provisions related to the Biomedical Research Commission; providing that the council serves as the exclusive source of biomedical research grant and fellowship awards; requiring the commission to create committees; requiring that the commission create policies and procedures related to committees and receiving input from outside sources; revising commission responsibilities; creating future requirement for the commission to submit lists of priorities for funding tobacco and non-tobacco-related diseases to the State Surgeon General; requiring State Surgeon General to provide commission funding priorities to the Legislature for funding; providing restrictions on the State Surgeon General; providing criteria for ranking priorities; providing for the award of grants or fellowships upon a specific appropriation; providing that

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funding is only available to research projects that go through the process set forth in the section; providing restrictions on the recommendation or award of grants or fellowships by other programs and entities; deleting references to conform to the changes made by this act; reducing the limits on administrative expenses; revising requirements relating the commission's annual progress report; providing a future expiration date for the commission to award grants for the Bankhead-Coley Program; revising provisions relating to appropriations; revising provisions relating to sunset of program; amending s. 381.79, F.S.; providing for the expiration of a provision relating to the distribution of funds from the Brain and Spinal Cord Injury Program Trust Fund; amending s. 381.853, F.S.; providing a requirement for the Florida Center for Brain Tumor Research relating to the use of state funds for biomedical research; amending s. 381.855, F.S.; providing additional program functions for the Florida Center for Universal Research to Eradicate Disease; requiring the Center to disseminate information about diseases and conditions to Floridians and providers if an appropriation is made; deleting cross references to conform to changes made by this act; amending s. 381.911, F.S.; deleting cross references to conform to changes made by this act; amending s. 381.912, F.S.; deleting cross references to conform to changes made by this act; requiring that recommendations be made to the Florida Center for Universal Research to Eradicate Disease where

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applicable to conform to the provisions of this act; amending s. 381.922, F.S.; deleting cross references to conform to changes of this act; revising the process and provisions related to awarding grants to conform to the changes to the biomedical research program in this act; revising process and provisions related to peer-review of grant applications to conform to the changes to the biomedical research program in this act; deleting cros references to conform to the changes made in this act; deleting provision concerning certification by the Division of Statutory Revision of the Office of Legislative Service related to the program; deleting provision concerning future Legislative review of program; revising sunset date for the program; amending s. 430.502, F.S.; requiring the Department of Elderly Affairs to evaluate the need for more memory disorder clinics in the state; deleting cross references to conform to changes made by this act; amending s. 430.503, F.S.; deleting cross references to conform to the changes made by this act; amending s. 430.504, F.S.; deleting cross references to conform to changes made by this act; amending s. 458.324, F.S.; deleting cross references and requirements to conform to changes made by this act; amending s. 459.0125, F.S.; deleting cross references and requirements to conform to changes made by this act; amending s. 1004.445, F.S.; providing for the future repeal of subsections to conform to changes made by this act; reducing appropriations for current year; specifying use

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of future appropriations beginning in 2009-2010; repealing s. 381.0404, F.S., relating to the Center for Health Technologies; repealing s. 381.85, F.S., relating to Biomedical and Social Research; repealing s. 381.912, F.S., relating to the Cervical Cancer Elimination Task Force; repealing s. 381.92, F.S., relating to the Florida Cancer Council; repealing s. 381.921, F.S., relating to the Florida Cancer Council mission and duties; repealing s. 381.98, F.S., relating to The Florida Public Health Foundation, Inc.; repealing s. 381.981, F.S., relating to Health awareness campaigns; repealing s. 430.501, F.S., relating to the Alzheimer's Disease Advisory Committee; repealing s. 1004.435, F.S., relating to cancer control and research and the Cancer Control and Research Commission; providing for severability; providing an effective date.

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Be It Enacted by the Legislature of the State of Florida:

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Section 1. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read:

20.435 Department of Health; trust funds.--

- (1) The following trust funds are hereby created, to be administered by the Department of Health:
  - (h) Biomedical Research Trust Fund.
- 1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to s. 215.5601 and any other funds appropriated by the Legislature. Funds shall be used for the

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- purposes of the James and Esther King Biomedical Research Program and the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program as specified in ss. 215.5602, 288.955, and 381.922. The trust fund is exempt from the service charges imposed by s. 215.20.
- 2. Funds deposited to the trust fund pursuant to s.

  215.5601 and any other funds appropriated by the Legislature as specified in ss. 215.5602(12)(a) and 288.955 or elsewhere for research related to tobacco-related diseases shall be used exclusively for the purpose of awarding grants and fellowships for research regarding the prevention, diagnosis, treatment, and cure of tobacco-related diseases by the James and Esther King Biomedical Research Program.
- 3. Funds deposited to the trust fund pursuant to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program as specified in s. 381.922 shall be used for the purpose of awarding grants for cancer research by the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.
- 4. All other funds deposited to the trust fund shall be used for the purpose of awarding grants and fellowship for biomedical research regarding the prevention, diagnosis, treatment, and cure of the most deadly and widespread nontobacco related acute, chronic, and degenerative diseases by the James and Esther King Biomedical Research Program as specified in ss. 215.5602(2)(b) and 215.5602(12)(b).
- 5.2. Notwithstanding the provisions of s. 216.301 and pursuant to s. 216.351, any balance in the trust fund at the end of any fiscal year shall remain in the trust fund at the end of

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the year and shall be available for carrying out the purposes of the trust fund. The department may invest these funds independently through the Chief Financial Officer or may negotiate a trust agreement with the State Board of Administration for the investment management of any balance in the trust fund.

- $\underline{6.3}$ . Notwithstanding s. 216.301 and pursuant to s. 216.351, any balance of any appropriation from the Biomedical Research Trust Fund which is not disbursed but which is obligated pursuant to contract or committed to be expended may be carried forward for up to  $\underline{5}$  years following the effective date of the original appropriation.
- Section 2. Section 215.5602, Florida Statutes, is amended to read:
  - 215.5602 James and 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 tobaccorelated cancer, cardiovascular disease, stroke, and pulmonary disease and non-tobacco related acute, chronic and degenerative diseases, including cancer, cardiovascular disease, stroke, pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease,

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epilepsy, and Parkinson's 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 the most deadly and widespread acute, chronic, and degenerative diseases, including, but not limited to tobacco-related diseases, cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's 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) Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of the most widespread acute, chronic and degenerative diseases affecting Floridians including, but not limited to, cancer, cardiovascular disease, stroke, pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.
- $\underline{\text{(d)}}$  (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.
- (e)(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.

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 $\underline{\text{(f)}}$  (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) (a) Funds appropriated for the James and Esther King
  Biomedical Research Program pursuant to the Lawton Chiles
  Endowment Fund in s. 215.5601 and additional funding provided in
  s. 215.5602(12)(a) or elsewhere in law for research related to
  tobacco-related diseases shall be credited to the Biomedical
  Research Trust Fund pursuant to s. 20.435 and shall be used
  exclusively for the award of grants and fellowships related 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 tobaccorelated disease.
- (b) Beginning in Fiscal Year 2009-2010 and each fiscal year thereafter, all other funds Funds appropriated for the James and Esther King Biomedical Research Program shall be credited to the Biomedical Research Trust Fund pursuant to s.

  20.435 and 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 the most deadly and widespread acute, chronic, and degenerative non-tobacco-related diseases affecting Floridians, related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic

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disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease; and for expenses incurred in the administration of this section. Priority shall be granted to research designed to prevent or cure non-tobacco related disease.

- (3) There is created within the Department of Health the Biomedical Research Commission Advisory Council.
- (a) The <u>commission council</u> shall consist of <u>15</u> <del>11</del> members, including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief executive officer of the <u>Greater Southeast Florida/Puerto Rico</u> 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 chief executive officer of the South Coastal Region of the American Diabetes Association, or a designee; and the president of the Florida Medical Association, or a designee. The remaining <u>10</u> <del>8</del> members of the <u>commission</u> 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 three two members, one member with expertise in the field of behavioral or social research and two representatives from volunteer health organizations operating in Florida that focus on Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or autoimmune or

genetic disorders one representative from a cancer program approved by the American College of Surgeons.

3. The Speaker of the House of Representatives shall appoint three two members, two representatives from volunteer health organizations operating in Florida that focus on Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or autoimmune or genetic disorders 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, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's 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) Except for the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program which expires June 30, 2011 as set forth in s. 381.922, beginning July 1, 2009, and each year thereafter, the biomedical research program shall serve as the exclusive source of awarding grants or fellowships for biomedical research in the state using state funds. This paragraph shall not preclude another grant or fellowship program

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in the state from awarding grants from funds received from private or federal sources where permitted by state law.

- (c) The commission shall create committees to focus on disease specific areas, including, but not limited to, tobaccorelated diseases, cancer, stroke, cardiovascular disease, pulmonary disease, diabetes, autoimmune or genetic disorders, Alzheimer's disease, epilepsy, and Parkinson's disease.
- (d) (b) The commission council shall adopt internal organizational procedures as necessary for its efficient organization, including policies and procedures regarding the creation and composition of the committees, reporting and recommendations by the committee to the commission regarding the award of grants and fellowships, coordination between the commission and committees, and the methods for receiving input from outside individuals, organizations or entities regarding the prioritization of research.
- (e) (c) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the <u>commission</u> <u>council</u> in carrying out its responsibilities, including those of its committees.
- (f)(d) Members of the <u>commission</u> 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, including committee meetings.
- (4) The <u>commission council</u> shall, after considering the <u>recommendations of its committees</u>, advise the State Surgeon General as to the direction and scope of the biomedical research

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program. The responsibilities of the <u>commission</u> <del>council may</del> include, but are not limited to:

- (a) <u>Establishing</u> <u>Providing advice on</u> program priorities and emphases.
- (b) <u>Evaluating Providing advice on</u> the overall program budget <u>and making recommendations to the State Surgeon General</u> and Legislature for future appropriations.
  - (c) Participating in periodic program evaluation.
- (d) <u>Developing</u> 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) <u>Developing</u> 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, <u>independent peer</u> review, and award of research grants and fellowships, to ensure an impartial, high-quality, science-based peer review system.
- (h) Developing and supervising <del>research</del> 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.

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- (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) For fiscal year 2008-2009, grants Grants and fellowships shall be awarded by the State Surgeon General, after consultation with the commission council, on the basis of scientific merit, as determined by an open competitive peer review process that ensures objectivity, consistency, and high quality.
- Beginning in 2010 and each year thereafter, the State Surgeon General shall submit to the Legislature by February 1 priority lists for both tobacco and non-tobacco related biomedical research funding by the Legislature based on the recommendations made by the commission after peer-review and scoring of the applications received. Recommendations to the Legislature shall be in the form of a list from the State Surgeon General of the commission's rank order of priority from the proposal with the highest priority through the proposal with the lowest priority, including the recommended dollar amount and duration for each proposal. The State Surgeon General shall not reject or modify the commission's recommendations. Successful applicants shall be awarded grants or fellowships by the State Surgeon General based upon the recommendations of the commission and the final funding decision made by the Legislature. for grant and fellowship applications for tobacco-related

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research	shall	be	based	upon	funds	available	pursuant	to	ss.
215.5601,	215.	5602	2(2)(a)	, and	1 216.5	5602(12)(a)	) <u>.</u>		

- (d) Beginning fiscal year 2009-2010 and each fiscal year thereafter, the commission's overall rank for grant or fellowship applications shall be based on the score awarded to the proposal by peer reviewers on the basis of scientific merit through an open competitive peer review process that ensures objectivity, consistency, and high quality, and the commission's determination of the following:
- 1. The projected impact that the proposed research will have on the most deadly and widespread diseases affecting

  Floridians at the time the grant or fellowship is awarded;
- 2. The likelihood or possibility that the proposed research will result in new treatment modalities or technology during the term of the grant or fellowship; and
- 3. Whether the research proposed offers an efficient use of state funds in order to prevent or cure disease.
- (e) 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.
- (f) The State Surgeon General shall award grants or fellowships for terms of 1 to 5 years. No state funds shall be provided for research that was not applied for, reviewed, and recommended in accordance with this section.
- (g) Except for the William G. "Bill" Bankhead, Jr., and
  David Coley Cancer Research Program which expires June 30, 2011

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as set forth in s. 381.922, beginning July 1, 2009 and each year thereafter, any program, board, commission, council, advisory group, agency or entity created by state law that awards or recommends the award of grants or fellowships for biomedical research shall cease awarding grants or fellowships using state funds and, instead, shall make recommendations to the commission and its committees for the prioritization and award of grants and fellowships through the James and Esther King Biomedical Research Program. This section shall not apply to the World Class Scholars, Centers of Excellence, or State University Research Commercialization Assistance Grant Programs as set forth in s. 1004.226.

- appropriate and are evaluated fairly on the basis of scientific merit, the State Surgeon General, in consultation with the <a href="mailto:commission">commission</a> 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 <a href="mailto:commission">commission</a> council and its committees and must be considered in determining which proposals shall be recommended for funding.
- (7) The <u>commission</u> <u>council</u>, the <u>committees</u> 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 <u>commission</u> <u>council</u>, a <u>committee</u>, 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

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member of the governing body or as an employee, or with which the member has entered into a contractual arrangement. Meetings of the <u>commission council</u>, the committees, 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. Effective July 1, 2009, administrative expenses may not exceed 10 percent of the total funds available to the program in any given year.
- (9) The department, after consultation with the <u>commission</u> council, may adopt rules <u>pursuant to ss. 120.536(1) and 120.54</u> as necessary to implement this section.
- Surgeon General and Legislature to appropriate money for the award of grants and fellowships, the commission 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 State Surgeon General, the President of the Senate, and the Speaker of the House of Representatives by February 1. The report must include:
- (a) A list of <u>current</u> 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 <u>peer-reviewed</u> <del>peer reviewed</del> 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 the most deadly and widespread diseases acute, chronic, and degenerative diseases affecting Floridians, including diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease.
- (11) The <u>commission</u> <u>council</u> shall award grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created in s. 381.922. <u>This</u> subsection shall expire June 30, 2011.
- (12) (a) 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 award of grants and fellowships by the James and Esther King Biomedical Research Program for research relating to tobacco-related diseases pursuant to this section. From these funds up to

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\$250,000 shall be available for the operating costs of the Florida Center for Universal Research to Eradicate Disease.

- (b) Beginning in fiscal year 2009-2010 and each fiscal year thereafter, the Legislature may appropriate funds from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for purposes of the award of grants and fellowships by the James and Esther King Biomedical Research Program for research of the most deadly and widespread non-tobacco related acute, chronic, and degenerative diseases pursuant to this section. Any research grant or fellowship awarded for Alzheimer's research pursuant to this section shall be named a "Johnnie B. Byrd, Sr. Alzheimer's Grant." Any research grant or fellowship awarded for cancer research pursuant to this section shall be named a "Bankhead-Coley Cancer Grant."
- (13) By June 1, 2014 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, 2016 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 2015 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, 2016 2011, unless reviewed and reenacted by the Legislature before that date.

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Section 3. Subsection (3) of section 381.79, Florida Statutes, is amended to read:

- 381.79 Brain and Spinal Cord Injury Program Trust Fund. --
- (3) Annually, 5 percent of the revenues deposited monthly in the fund pursuant to s. 318.21(2)(d) shall be appropriated to the University of Florida and 5 percent to the University of Miami for spinal cord injury and brain injury research. The amount to be distributed to the universities shall be calculated based on the deposits into the fund for each quarter in the fiscal year, but may not exceed \$500,000 per university per year. Funds distributed under this subsection shall be made in quarterly payments at the end of each quarter during the fiscal year. This subsection expires June 30, 2009.
- Section 4. Paragraph (h) is added to subsection (4) of section 381.853, Florida Statutes, to read:
  - 381.853 Florida Center for Brain Tumor Research. --
- (4) The Florida Center for Brain Tumor Research is established within the Evelyn F. and William L. McKnight Brain Institute of the University of Florida.
- (h) Beginning in fiscal year 2009-2010 and each fiscal year thereafter, if the center seeks to conduct biomedical research using state funds, the center shall apply for funding through the James and Esther King Biomedical Research Program pursuant to s. 215.5602.
- Section 5. Paragraphs (n) through (p) are added to subsection (3), and paragraph (a) of subsection (5) of section 381.855, Florida Statutes, is amended to read:

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381.855 Florida Center for Universal Research to Eradicate Disease.--

- (3) There is established within the Department of Health the Florida Center for Universal Research to Eradicate Disease, which shall be known as "CURED."
- (a) The purpose of the center is to coordinate, improve, expand, and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread public use.
- (b) The goal of the center is 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.
- (c) The center shall hold an annual biomedical technology summit in Florida to which biomedical researchers, biomedical technology companies, business incubators, pharmaceutical manufacturers, and others around the nation and world are invited to share biomedical research findings in order to expedite the discovery of cures. Summit attendees shall cover the costs of such attendance or obtain sponsorship for such attendance.
- (d) The center shall encourage clinical trials in this state on research that holds promise of curing a disease or condition. The center shall facilitate partnerships between researchers, treating physicians, and community hospitals for the purpose of sharing new techniques and new research findings,

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as well as coordinating voluntary donations to ensure an adequate supply of adult stem cells, placentas, or cord blood.

- (e) The center shall facilitate the formation of partnerships between researchers in this state and institutions in other states and countries where research with rare plants or animals could lead to cures.
- (f) The center shall encourage agricultural colleges and agricultural businesses in this state to be active in the search for cures and in providing information to the public about disease prevention.
- (g) The center shall facilitate partnerships among researchers working to cure all types of diseases, including those that are prevalent in developed countries and those that occur mainly in developing countries.
- (h) The center shall also encourage the discovery and production in Florida of vaccines that prevent disease.
- (i) The center shall monitor the supply and demand needs of researchers relating to stem cell research and other types of human tissue research. If the center determines that there is a need for increased donation of human tissue, it shall notify hospitals licensed pursuant to chapter 395 which have entered into partnership agreements with research institutes conducting stem cell research located in the same geographic region as the researchers demanding the stem cells or other tissues. Such hospitals shall implement programs that encourage voluntary donations of cord blood or other needed adult tissue.
- (j) The center shall be funded through private, state, and federal sources.

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- (k) The center shall serve as a registry of all known opportunities for biomedical grants and may assist any public or private biomedical research program in this state in preparing grant requests.
- (1) The center shall maintain a website with links to peer-reviewed biomedical research. The website shall also contain a list of all known biomedical research being conducted in Florida and shall facilitate communication among researchers and other interested parties.
- (m) The center shall submit an annual report to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than January 15 which contains recommendations for legislative change necessary to foster a positive climate for biomedical research in this state.
- (n) The center shall identify ways to attract new research talent and attendant national grant producing researchers to research facilities in this state.
- (o) If funds are specifically appropriated by the Legislature, the center shall disseminate information to Floridians and treatment providers about specified diseases and conditions and available methods of preventing, diagnosing, treating, and curing those diseases and conditions.
- (p) The center shall provide information regarding research needs in the state to the Biomedical Research Commission located in the James and Esther King Biomedical Research Program.
- (5) There is established within the center an advisory council that shall meet at least annually.

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- (a) The council shall consist of one representative from a Florida not-for-profit institution engaged in basic and clinical biomedical research and education which receives more than \$10 million in annual grant funding from the National Institutes of Health, to be appointed by the State Surgeon General from a different institution each term, and one representative from and appointed by each of the following entities:
  - 1. Enterprise Florida, Inc.
  - 2. BioFlorida.

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- 3. The Biomedical Research Commission Advisory Council.
- 4. The Florida Medical Foundation.
- 5. Pharmaceutical Research and Manufacturers of America.
- 6. The Florida Cancer Council.
- 6.7. The American Cancer Society, Florida Division, Inc.
- 7.8. The American Heart Association.
- 624 8.<del>9.</del> The American Lung Association of Florida.
- 625 <u>9.10.</u> The American Diabetes Association, South Coastal Region.
- 627 10.<del>11.</del> The Alzheimer's Association.
  - 11.<del>12.</del> The Epilepsy Foundation.
- 629 12.<del>13.</del> The National Parkinson Foundation.
- 630 14. The Florida Public Health Foundation, Inc.
- 631 13.<del>15.</del> The Florida Research Consortium.
- Section 6. Subsection (2), subsection (3), and subsection
- 633 (4) of section 381.911, Florida Statutes, are amended to read:
- 634 381.911 Prostate Cancer Awareness Program.--

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- (2) For purposes of implementing the program, the Department of Health and the Florida Public Health Foundation, Inc., may:
- (a) Conduct activities directly or enter into a contract with a qualified nonprofit community education entity.
- (b) Seek any available gifts, grants, or funds from the state, the Federal Government, philanthropic foundations, and industry or business groups.
- (3) A prostate cancer advisory committee is created to advise and assist the Department of Health and the Florida Public Health Foundation, Inc., in implementing the program.
- (a) The State Surgeon General shall appoint the advisory committee members, who shall consist of:
- 1. Three persons from prostate cancer survivor groups or cancer-related advocacy groups.
- 2. Three persons who are scientists or clinicians from public universities or research organizations.
- 3. Three persons who are engaged in the practice of a cancer-related medical specialty from health organizations committed to cancer research and control.
- (b) Members shall serve without compensation but are entitled to reimbursement, pursuant to s. 112.061, for per diem and travel expenses incurred in the performance of their official duties.
- (4) The program shall coordinate its efforts with those of the Florida Public Health Foundation, Inc.
- Section 7. Subsections (2), (3), (5), (6), (7) and (8) of section 381.922, Florida Statutes, are amended to read:

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

- (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.  $\frac{381.921}{\text{ as those}}$  goals that 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.
- (b) For fiscal year 2008-2009, grants Grants shall be awarded by the State Surgeon General, after consultation with the Biomedical Research Commission Advisory Council, on the basis of scientific merit through, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality.
- (c) Beginning in fiscal year 2009-2010 and each fiscal year thereafter, the State Surgeon General shall submit to the Legislature by February 1 a priority list for cancer research

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funding by the Legislature based on the recommendations made by						
the commission after peer-review and scoring of the applications						
received. Recommendations to the Legislature shall be in the						
form of a list from the State Surgeon General of the						
commission's rank order of priority from the proposal with the						
highest priority through the proposal with the lowest priority,						
including the recommended dollar amount and duration for each						
proposal. The State Surgeon General shall not reject or modify						
the commission's recommendations. Successful applicants shall						
be awarded grants by the State Surgeon General based upon the						
recommendations of the commission and the final funding decision						
made by the Legislature.						

- (d) Beginning in fiscal year 2009-2010 and each fiscal year thereafter, the commission's overall rank for grant or fellowship applications shall be based on the score awarded to the proposal by peer reviewers on the basis of scientific merit through an open competitive peer review process that ensures objectivity, consistency, and high quality, and the commission's determination of the following:
- 1. The projected impact that the proposed research will have on cancer research at the time the grant is awarded;
- 2. The likelihood or possibility that the proposed research will result in new treatment modalities or technology during the term of the grant; and
- 3. Whether the research proposed offers an efficient use of state funds in order to prevent or cure cancer.
- (e) The following types of applications shall be considered for funding:

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- 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.
- (f) Beginning in fiscal year 2009-2010 and each fiscal year thereafter, no state funds shall be provided for research that was not applied for, reviewed, and recommended in accordance with this section.
- (g) (b) In order to ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the State Surgeon General, in consultation with the commission 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 commission and its committees council and must be considered in determining which proposals shall be recommended for funding.
- (h) (c) The commission, council the committees 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 commission, council a committee 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 commission, council the committees and the peer review

panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

- (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.
- (6) (8) This section expires June 30 January 1, 2011, unless reviewed and reenacted by the Legislature before that date.
- Section 8. Subsection (3) of section 430.502, Florida Statutes, is amended to read:

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430.502 Alzheimer's disease; memory disorder clinics and day care and respite care programs.--

- Advisory Committee must shall consult with the Alzheimer's Disease Disease Brain Bank and model day care programs to evaluate the need for additional memory disorder clinics in the state. The first report will be due by December 31, 1995.
- Section 9. Subsection (2) of section 430.503, Florida Statutes, is amended to read:
- 430.503 Alzheimer's Disease Initiative; fees and administrative expense.--
- (2) Provider agencies are responsible for the collection of fees for services in accordance with rules adopted by the department. Provider agencies shall assess fees for services rendered in accordance with those rules. To help pay for services received pursuant to the Alzheimer's Disease Initiative, a functionally impaired elderly person shall be assessed a fee based on an overall ability to pay. The fee to be assessed shall be fixed according to a schedule to be established by the department. Services of specified value may be accepted in lieu of a fee. The fee schedule shall be developed in cooperation with the Alzheimer's Disease Advisory Committee, area agencies on aging, and service providers.

Section 10. Section 430.504, Florida Statutes, is amended to read:

430.504 Confidentiality of information.--Information about clients of programs created or funded under s. 430.501 or s. 430.503 which is received through files, reports, inspections,

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or otherwise, by the department or by authorized departmental employees, by persons who volunteer services, or by persons who provide services to clients of programs created or funded under s. 430.501 or s. 430.503 through contracts with the department is confidential and exempt from the provisions of s. 119.07(1). Such information may not be disclosed publicly in such a manner as to identify a person who receives services under s. 430.501 or s. 430.503, unless that person or that person's legal guardian provides written consent.

Section 11. Subsection (1) and paragraph (a) of subsection (2) of section 458.324, Florida Statutes, are amended to read:

458.324 Breast cancer; information on treatment alternatives.--

- (1) DEFINITION.--As used in this section, the term "medically viable," as applied to treatment alternatives, means modes of treatment generally considered by the medical profession to be within the scope of current, acceptable standards, including treatment alternatives described in the written summary prepared by the Florida Cancer Control and Research Advisory Council in accordance with s. 1004.435(4)(m).
- (2) COMMUNICATION OF TREATMENT ALTERNATIVES.--Each physician treating a patient who is, or in the judgment of the physician is at high risk of being, diagnosed as having breast cancer shall inform such patient of the medically viable treatment alternatives available to such patient; shall describe such treatment alternatives; and shall explain the relative advantages, disadvantages, and risks associated with the treatment alternatives to the extent deemed necessary to allow

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the patient to make a prudent decision regarding such treatment options. In compliance with this subsection:

- (a) The physician may, in his or her discretion:
- 1. Orally communicate such information directly to the patient or the patient's legal representative;
- 2. Provide the patient or the patient's legal representative with a copy of <u>a</u> the written summary <del>prepared in accordance with s. 1004.435(4) (m)</del> and express a willingness to discuss the summary with the patient or the patient's legal representative; or
- 3. Both communicate such information directly and provide a copy of the written summary to the patient or the patient's legal representative for further consideration and possible later discussion.

Nothing in this subsection shall reduce other provisions of law regarding informed consent.

Section 12. Subsection (1) and paragraph (a) of subsection (2) of section 459.0125, Florida Statutes, are amended to read:
459.0125 Breast cancer; information on treatment

alternatives.--

- "medically viable," as applied to treatment alternatives, means modes of treatment generally considered by the medical profession to be within the scope of current, acceptable standards, including treatment alternatives described in the written summary prepared by the Florida Cancer Control and Research Advisory Council in accordance with s. 1004.435(4)(m).
  - (2) COMMUNICATION OF TREATMENT ALTERNATIVES. -- It is the

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obligation of every physician treating a patient who is, or in the judgment of the physician is at high risk of being, diagnosed as having breast cancer to inform such patient of the medically viable treatment alternatives available to such patient; to describe such treatment alternatives; and to explain the relative advantages, disadvantages, and risks associated with the treatment alternatives to the extent deemed necessary to allow the patient to make a prudent decision regarding such treatment options. In compliance with this subsection:

- (a) The physician may, in her or his discretion:
- 1. Orally communicate such information directly to the patient or the patient's legal representative;
- 2. Provide the patient or the patient's legal representative with a copy of  $\underline{a}$  the written summary prepared in accordance with s. 1004.435(4) (m) and express her or his willingness to discuss the summary with the patient or the patient's legal representative; or
- 3. Both communicate such information directly and provide a copy of the written summary to the patient or the patient's legal representative for further consideration and possible later discussion.
- Nothing in this subsection shall reduce other provisions of law regarding informed consent.
- Section 13. Paragraph (e) of subsection (8) is added, and subsections (7) and (12) of section 1004.445, Florida Statutes, are amended to read:
- 884 1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and 885 Research Institute.--

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(7) The board of directors of the not-for-profit corporation shall create a council of scientific advisers to the chief executive officer comprised of leading researchers, physicians, and scientists. The council shall review programs and recommend research priorities and initiatives to maximize the state's investment in the institute. The members of the council shall be appointed by the board of directors of the not-for-profit corporation. Each member of the council shall be appointed to serve a 2-year term and may be reappointed to the council. This subsection shall expire on June 30, 2009.

(8)

- (e) This subsection shall expire June 30, 2009.
- (12) (a) Beginning in fiscal year 2008-2009 2007-2008, the sum of \$5 \$13.5 million is appropriated annually from recurring funds in the General Revenue Fund to the Grants and Donations Trust Fund within the Department of Elderly Affairs for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida for the purposes as provided under paragraph (6)(a), conducting and supporting research, 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. Not less than 80 percent of the appropriated funds shall be expended for these purposes, and not less than 20 percent of the appropriated funds shall be expended for peer-reviewed investigator-initiated research grants.
  - (b) Beginning in fiscal year 2009-2010 and each fiscal

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year thereafter, the sum appropriated in paragraph (12)(a) shall							
be used for programs that fulfill the mission of the institute							
in 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. If the institute intends to conduct							
research using state funds, it shall compete for funding through							
the James and Esther King Biomedical Research Program pursuant							
to s. 215.5602, F.S.							

Section 14. Sections 381.0404, 381.85, 381.912,381.92, 381.921, 381.98, 381.981, 430.501, and 1004.435, Florida Statutes, are repealed.

Section 15. If any provision of this act or the application thereof to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of the act which can be given effect without the invalid provision or application, and to this end the provisions of this act are declared severable.

Section 16. This act shall take effect July 1, 2008.