By Senator Saunders

37-59A-06 See HB

1	A bill to be entitled
2	An act relating to biomedical research;
3	providing legislative intent; amending s.
4	215.5602, F.S.; revising the method for
5	appointing members to the Biomedical Research
6	Advisory Council; authorizing the Legislature
7	to annually appropriate funds to the James and
8	Esther King Biomedical Research Program;
9	providing for transition to new appointments;
10	amending s. 381.855, F.S.; revising the purpose
11	of the Florida Center for Universal Research to
12	Eradicate Disease; requiring the center to
13	provide grants for cancer research; revising
14	membership of the center's advisory council;
15	providing for terms of office and the filling
16	of vacancies; providing for officers, meetings,
17	and procedure; providing procedures for
18	awarding of cancer research grants; providing
19	for peer review panels; providing requirements
20	with respect to ethical conduct and conflicts
21	of interest; providing for public records and
22	meetings; authorizing the Legislature to
23	annually appropriate funds to the Florida
24	Center for Universal Research to Eradicate
25	Disease; providing for transition to new
26	appointments; amending s. 381.921, F.S.;
27	revising a goal of the Florida Cancer Council;
28	creating s. 381.922, F.S.; establishing the
29	William G. "Bill" Bankhead, Jr., and David
30	Coley Cancer Research Program within the
31	Department of Health; providing the purpose of

the program; requiring an annual report; amending s. 561.121, F.S.; redistributing certain funds collected from taxes on alcoholic beverages; amending s. 1004.445, F.S.; revising the method of appointing and filling vacancies on the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; requiring certain information in the annual report; requiring an annual operating budget; providing procedures for awarding of Alzheimer's disease research grants; providing for peer review panels; providing requirements with respect to ethical conduct, conflicts of interest, and confidentiality; providing for public records and meetings; authorizing the Legislature to annually appropriate funds to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute; providing for transition to new appointments; providing appropriations; providing effective dates.

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

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Section 1. It is the intent of the Legislature to provide funding to support grants for biomedical research in this state with the anticipation that sustained funding for biomedical research over a period of years will lead to an alleviation of human suffering from diseases such as cancer and Alzheimer's disease. It is the intent of the Legislature to dramatically reduce this state's inordinately high cancer burden, reducing both cancer incidence and mortality, while

advancing scientific endeavors in this state, making this 2 state a world-class leader in cancer research and treatment. Further, it is the intent of the Legislature to address the 3 4 debilitating and deadly effects of Alzheimer's disease by 5 supporting research in Alzheimer's disease statewide through 6 the awarding of research grants on a competitive basis. 7 Additionally, it is the intent of the Legislature to stimulate dramatic economic development, particularly in the 8 biotechnology industry, through investment in this state's 9 10 biomedical research. Section 2. Subsection (3) of section 215.5602, Florida 11 12 Statutes, is amended, and subsection (11) is added to that 13 section, to read: 215.5602 James and Esther King Biomedical Research 14 15 Program. --(3) There is created within the Department of Health 16 17 the Biomedical Research Advisory Council. 18 (a) The council shall consist of nine members, including: the chief executive officer of the Florida Division 19 2.0 of the American Cancer Society, or a designee; the chief 21 executive officer of the Florida/Puerto Rico Affiliate of the 2.2 American Heart Association, or a designee; and the chief 23 executive officer of the American Lung Association of Florida, or a designee. The Governor shall appoint the remaining six 2.4 members of the council, shall be appointed as follows: 2.5 1. The Governor shall appoint two members with 26 27 expertise in the field of biomedical research, one member from 2.8 a research university in the state, and one member representing the general population of the state. 29

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2. The President of the Senate shall appoint one member with expertise in the field of behavioral or social research.

3. The Speaker of the House of Representatives shall appoint one member from a professional medical organization.

4. One member from a research university in the state.

5. One member representing the general population of the state.

In making these his or her appointments, the Governor, the President of the Senate, and the Speaker of the House of Representatives shall select primarily, but not exclusively, Floridians with biomedical and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease. The Governor's appointments shall be for a 3-year term and shall reflect the diversity of the state's population. An appointed A council member appointed by the Governor may not serve more than two consecutive terms.

- (b) The council shall adopt internal organizational procedures as necessary for its efficient organization.
- (c) The department shall provide such staff, information, and other assistance as is reasonably necessary to assist the council in carrying out its responsibilities.
- (d) Members of the council shall serve without compensation, but may receive reimbursement as provided in s. 112.061 for travel and other necessary expenses incurred in the performance of their official duties.
- (11) The Legislature may annually appropriate funds to the James and Esther King Biomedical Research Program for the purposes of this section.

Section 3. All appointments to the Biomedical Research Advisory Council for the James and Esther King Biomedical 2 Research Program that were not made in accordance with s. 3 4 215.5602, Florida Statutes, as amended by this act, shall expire June 30, 2006, but such appointees may continue to 5 serve until their successors are appointed. This section shall 7 take effect upon this act becoming a law. Section 4. Subsections (3) and (5) of section 381.855, 8 9 Florida Statutes, are amended, and subsections (6), (7), (8), and (9) are added to that section, to read: 10 381.855 Florida Center for Universal Research to 11 12 Eradicate Disease. --13 (3) There is established within the Department of Health the Florida Center for Universal Research to Eradicate 14 Disease, which shall be known as "CURED." 15 (a) The purpose of the center is to coordinate, 16 17 improve, expand, and monitor all biomedical research programs 18 within the state, facilitate funding opportunities, including providing grants for cancer research through the William G. 19 "Bill" Bankhead, Jr., and David Coley Cancer Research Program 20 21 created in s. 381.922, and foster improved technology transfer 22 of research findings into clinical trials and widespread 23 public use. (b) The goal of the center is to find cures for 2.4 diseases such as cancer, heart disease, lung disease, 2.5 26 diabetes, autoimmune disorders, and neurological disorders, 27 including Alzheimer's disease, epilepsy, and Parkinson's 2.8 disease. (c) The center shall hold an annual biomedical 29 30 technology summit in Florida to which biomedical researchers,

biomedical technology companies, business incubators,

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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, 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

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

(m)(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.

 $\underline{\text{(n)}(m)}$  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.

- (5) There is established within the center an advisory council that shall meet at least annually.
- 6 (a) The council shall consist of one representative 7 from a Florida not-for-profit institution engaged in basic and clinical biomedical research and education which receives more 8 than \$10 million in annual grant funding from the National 9 10 Institutes of Health, to be appointed by the Secretary of Health from a different institution each term, and the members 11 of the board of directors of the Florida Research Consortium 12 13 and at least one representative from and appointed by each of the following entities: 14
  - 1. The Emerging Technology Commission.
- 16 2. Enterprise Florida, Inc.
- 17 3. BioFlorida.
  - 4. The Biomedical Research Advisory Council.
- 19 5. The Florida Medical Foundation.
- 20 6. Pharmaceutical Research and Manufacturers of
- 21 America.

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- 7. The Florida Tri-Agency Coalition on Smoking OR
- 23 Health.
- 8. The Florida Cancer Council.
- 25 9. The American Cancer Society, Florida Division, Inc.
- 26 10. The American Heart Association.
- 27 11. The American Lung Association of Florida.
- 28 12. The American Diabetes Association, South Coastal
- 29 Region.
- 30 13. The Alzheimer's Association.
- 31 14. The Epilepsy Foundation.

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considered for funding:

- 15. The National Parkinson Foundation.
  - 16. The Florida Public Health Foundation, Inc.
  - 17. The Florida Research Consortium Scripps Florida or the entity formed in this state by The Scripps Research

    Institute.
  - (b) Members of the council shall serve without compensation, and each organization represented shall cover all expenses of its representative.
  - (6) Members shall be appointed to 4-year terms of office. The members of the advisory council shall annually elect a chair from among the members of the advisory council.

    Any vacancy on the advisory council shall be filled in the same manner as the original appointment.
  - (7) The advisory council shall meet at least annually, but may meet as often as it deems necessary to carry out its duties and responsibilities. The advisory council may take official action by a majority vote of the members present at any meeting at which a quorum is present.
  - (8)(a) Applications for cancer research funding may be submitted from 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 center's goals enumerated in paragraph (3)(1), may be given preference. Grants shall be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high

quality. The following types of applications shall be

1. Investigator-initiated research grants. 2 Institutional research grants. 3 3. Collaborative research grants, including those that 4 advance the finding of cures through basic or applied 5 research. 6 (b) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of 8 scientific merit, the Secretary of Health, in consultation with the council, shall appoint a peer review panel of 9 10 independent, scientifically qualified individuals to review the scientific content of each proposal and establish its 11 scientific priority score. The priority scores shall be 12 13 forwarded to the council and must be considered in determining which proposals shall be recommended for funding. 14 (c) The council and the peer review panel shall 15 establish and follow rigorous quidelines for ethical conduct 16 and adhere to a strict policy with regard to conflict of 18 interest. A member of the council or panel may not participate in any discussion or decision with respect to a research 19 2.0 proposal by any firm, entity, or agency with which the member 21 is associated as a member of the governing body or as an employee or with which the member has entered into a 2.2 23 contractual arrangement. Meetings of the council and the peer review panels are subject to chapter 119, s. 286.011, and s. 2.4 24, Art. I of the State Constitution. 2.5 (9) The Legislature may annually appropriate funds to 26 2.7 the Florida Center for Universal Research to Eradicate Disease 2.8 for research grants and for operating costs. 29 Section 5. All appointments to the advisory council for the Florida Center for Universal Research to Eradicate 30 Disease that were not made in accordance with s. 381.855, 31

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Florida Statutes, as amended by this act, shall expire June

30, 2006, but such appointees may continue to serve until

their successors are appointed. This section shall take effect

upon this act becoming a law.

Section 6. Subsection (1) of section 381.921, Florida Statutes, is amended to read:

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

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

(f) Aiding in other multidisciplinary research-support 2 activities as they inure to the advancement of cancer 3 research. 4 Section 7. Section 381.922, Florida Statutes, is created to read: 5 6 381.922 William G. "Bill" Bankhead, Jr., and David 7 Coley Cancer Research Program. --(1) The William G. "Bill" Bankhead, Jr., and David 8 Coley Cancer Research Program, which may be otherwise cited as 9 10 the "Bankhead-Coley Program," is created within the Department of Health. The purpose of the program shall be to advance 11 12 progress towards cures for cancer through grants awarded 13 through a peer-reviewed, competitive process pursuant to s. 381.855. 14 (2) By December 15 of each year, the Department of 15 Health shall submit to the Governor, the President of the 16 17 Senate, and the Speaker of the House of Representatives a 18 report indicating progress towards the program's mission and making recommendations that further its purpose. 19 2.0 Section 8. Subsection (1) of section 561.121, Florida 21 Statutes, is amended to read: 22 561.121 Deposit of revenue.--23 (1) All state funds collected pursuant to ss. 563.05, 564.06, and 565.12 shall be paid into the State Treasury and 2.4 disbursed in the following manner: 2.5 (a) 1. Two percent of monthly collections of the excise 26 27 taxes on alcoholic beverages established in ss. 563.05, 2.8 564.06, and 565.12 shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund to meet the division's 29 30 appropriation for the state fiscal year.

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the university.

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distributed \$15 million to the Grants and Donations Trust Fund within the Department of Elderly Affairs, and these funds are annually appropriated to support a contract with the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida for the purposes of conducting research, developing and operating integrated data projects, and providing assistance to memory disorder clinics as established in s. 430.502. 3. Beginning July 1, 2004, there is annually distributed \$6 million to the Biomedical Research Trust Fund within the Department of Health, and these funds are annually appropriated to the James and Esther King Biomedical Research Program. From these funds, up to \$250,000 shall be available annually for the operating costs of the Florida Center for Universal Research to Eradicate Disease. 4. Beginning July 1, 2004, there is annually distributed \$9 million to be paid by warrant drawn by the Chief Financial Officer upon the State Treasury to Florida State University for the School of Chiropractic Medicine. Notwithstanding the provisions of chapter 216, until the School of Chiropractic Medicine is completely staffed and fully operational, these funds may be used for any purpose by

2. Beginning July 1, 2004, there is annually

(b) The remainder of the funds collected pursuant to

ss. 563.05, 564.06, and 565.12 collection shall be credited to

Section 9. Subsections (2) and (6) of section 1004.445, Florida Statutes, are amended, present subsections

(8), (9), and (10) are renumbered as subsections (9), (10),

and (11), respectively, and new subsections (8) and (12) are 2 added to that section, to read: 1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and 3 Research Institute. --4 5 (2)(a) The State Board of Education shall enter into 6 an agreement for the utilization of the facilities on the 7 campus of the University of South Florida to be known as the 8 Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, including all furnishings, equipment, and other 9 chattels used in the operation of those facilities, with a 10 Florida not-for-profit corporation organized solely for the 11 purpose of governing and operating the Johnnie B. Byrd, Sr., 13 Alzheimer's Center and Research Institute. This not-for-profit corporation, acting as an instrumentality of the state, shall 14 govern and operate the Johnnie B. Byrd, Sr., Alzheimer's 15 Center and Research Institute in accordance with the terms of 16 the agreement between the State Board of Education and the 18 not-for-profit corporation. The not-for-profit corporation may, with the prior approval of the State Board of Education, 19 create either for-profit or not-for-profit corporate 20 21 subsidiaries, or both, to fulfill its mission. The 22 not-for-profit corporation and its subsidiaries are authorized 23 to receive, hold, invest, and administer property and any moneys acquired from private, local, state, and federal 2.4 sources, as well as technical and professional income 25 26 generated or derived from practice activities of the 27 institute, for the benefit of the institute and the 2.8 fulfillment of its mission. 29 (b) The affairs of the not-for-profit corporation 30 shall be managed by a board of directors who shall serve without compensation. The board of directors shall consist of

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the President of the University of South Florida and the chair of the State Board of Education, or their designees, <u>five</u> 5 representatives of the state universities, and <u>nine</u> no fewer than 9 nor more than 14 representatives of the public who are neither medical doctors nor state employees. Each director who is a representative of a state university or of the public shall be appointed to serve a term of 3 years. The chair of the board of directors shall be selected by a majority vote of the directors. Each director shall have only one vote.

2. The initial board of directors shall consist of the President of the University of South Florida and the chair of the State Board of Education, or their designees; the Of the five university representatives, of whom one shall be appointed by the Governor, two by the President of the Senate, and two by the Speaker of the House of Representatives; and of the nine public representatives, of whom three shall be appointed by the Governor, three by the President of the Senate, and three by the Speaker of the House of Representatives. Upon the expiration of the terms of the initial appointed directors, all directors subject to 3 year terms of office under this paragraph shall be appointed by a majority vote of the directors and the board may be expanded to include additional public representative directors up to the maximum number allowed. Any vacancy in office shall be filled in the same manner as the original appointment for the remainder of the term by majority vote of the directors. Any director may be reappointed.

(6) The institute shall be administered by a chief executive officer, who shall be appointed by and serve at the pleasure of the board of directors of the not-for-profit

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corporation, and who shall exercise the following powers and duties, subject to the approval of the board of directors:

- (a) The chief executive officer shall establish programs that fulfill the mission of the institute in research, education, treatment, prevention, and early detection of Alzheimer's disease; however, the chief executive officer may not establish academic programs for which academic credit is awarded and which culminate in the conferring of a degree, without prior approval of the State Board of Education.
- (b) The chief executive officer shall have control over the budget and the moneys appropriated or donated to the institute from private, local, state, and federal sources, as well as technical and professional income generated or derived from practice activities of the institute. However, professional income generated by university faculty from practice activities at the institute shall be shared between the institute and the university as determined by the chief executive officer and the appropriate university dean or vice president.
- (c) The chief executive officer shall appoint representatives of the institute to carry out the research, patient care, and educational activities of the institute and establish the compensation, benefits, and terms of service of such representatives. Representatives of the institute shall be eligible to hold concurrent appointments at affiliated academic institutions. University faculty shall be eligible to hold concurrent appointments at the institute.
- (d) The chief executive officer shall have control over the use and assignment of space and equipment within the facilities.

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considered for funding:

- (e) The chief executive officer shall have the power to create the administrative structure necessary to carry out the mission of the institute.
- (f) The chief executive officer shall have a reporting relationship to the Commissioner of Education.
- (g) The chief executive officer shall provide a copy of the institute's annual report to the Governor and Cabinet, the President of the Senate, the Speaker of the House of Representatives, and the chair of the State Board of Education. The annual report shall describe the expenditure of all funds and shall provide information regarding research that has been conducted or funded by the center, as well as the expected and actual results of such research.
- (h) By August 1 of each year, the chief executive officer shall develop and submit to the Governor and Cabinet, the President of the Senate, the Speaker of the House of Representatives, and the chair of the State Board of Education an annual operating budget detailing the planned use of state, federal, and private funds for the fiscal year.

(8)(a) Applications for Alzheimer's disease research funding may be submitted from 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. Grants shall be awarded by the board of directors of the not-for-profit corporation, after consultation with the CURED advisory council created under s. 381.855, on the basis of scientific merit, as determined by an open, competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be

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2 Institutional research grants. 3 (b) To ensure that all proposals for research funding 4 are appropriate and are evaluated fairly on the basis of 5 scientific merit, the board of directors of the not-for-profit 6 corporation, in consultation with the council of scientific 7 advisors, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific 8 content of each proposal and establish its scientific priority 9 10 score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be 11 12 recommended for funding. 13 (c) The council of scientific advisors and the peer review panel shall establish and follow rigorous quidelines 14 for ethical conduct and adhere to a strict policy with regard 15 to conflict of interest and confidentiality which shall comply 16 with National Institutes of Health standards. All employees, 18 members of the board of directors, and affiliates of the not-for-profit corporation shall follow the same rigorous 19 quidelines for ethical conduct and shall adhere to the same 2.0 21 strict policy with regard to conflict of interest and confidentiality. A member of the council or panel may not 2.2 23 participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which 2.4

Investigator-initiated research grants.

(12) The Legislature may annually appropriate funds to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research

the member is associated as a member of the governing body or

contractual arrangement. Meetings of the council and the peer

review panels are subject to chapter 119, s. 286.011, and s.

24, Art. I of the State Constitution.

as an employee or with which the member has entered into a

Institute at the University of South Florida for the purposes 2 of this section. Section 10. All appointments to the board of directors 3 4 of the not-for-profit corporation for the Johnnie B. Byrd, 5 Alzheimer's Center and Research Institute that were not 6 made in accordance with s. 1004.445, Florida Statutes, as 7 amended by this act, shall expire June 30, 2006, but such 8 appointees may continue to serve until their successors are appointed. This section shall take effect upon this act 9 10 becoming a law. Section 11. (1) The sum of \$6 million is appropriated 11 12 from the General Revenue Fund to the Biomedical Research Trust 13 Fund in the Department of Health for fiscal year 2006-2007 for purposes of the James and Esther King Biomedical Research 14 Program pursuant to s. 215.5602, Florida Statutes. 15 (2) The sum of \$9 million is appropriated from the 16 17 General Revenue Fund to the Florida Center for Universal 18 Research to Eradicate Disease within the Department of Health for fiscal year 2006-2007 to be distributed pursuant to s. 19 381.855, Florida Statutes, to provide grants to researchers 2.0 21 seeking cures for cancer, with emphasis given to the goals enumerated in s. 381.921, Florida Statutes. 2.2 23 (3) The sum of \$15 million is appropriated from the General Revenue Fund to the Johnnie B. Byrd, Sr., Alzheimer's 2.4 Center and Research Institute at the University of South 2.5 Florida for fiscal year 2006-2007 for the purposes of 26 27 conducting research, developing and operating integrated data 2.8 projects, and providing assistance to memory disorder clinics as provided under s. 430.502, Florida Statutes. Not less than 29 30 80 percent of these funds shall be distributed by the center

as institutional research grants or investigator-initiated research grants. Section 12. Except as otherwise expressly provided in this act and except for this section, which shall take effect upon this act becoming a law, this act shall take effect July 1, 2006.