## CHAMBER ACTION

The Health Care Appropriations Committee recommends the following:

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## Council/Committee Substitute

Remove the entire bill and insert:

A bill to be entitled

An act relating to biomedical research; providing legislative intent; amending s. 20.435, F.S.; authorizing the use of funds in the Biomedical Research Trust Fund for the purposes of the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; amending s. 215.5602, F.S.; revising the membership and the method for appointing members to the Biomedical Research Advisory Council; requiring the council to award grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; authorizing the Legislature to annually appropriate funds to the James and Esther King Biomedical Research Program; providing for transition to new appointments; amending s. 381.855, F.S.; revising the membership of the advisory council for the Florida Center for Universal Research to Eradicate Disease; providing for terms of office and the filling of vacancies; providing for officers, meetings, and

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procedures; authorizing the Legislature to annually appropriate funds to the Florida Center for Universal Research to Eradicate Disease; providing for transition to new appointments; amending s. 381.921, F.S.; revising a goal of the Florida Cancer Council; creating s. 381.922, F.S.; establishing the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program within the Department of Health; providing the purpose of the program; requiring the program to provide grants for cancer research; providing procedures for awarding cancer research grants; providing for peer-review panels; providing requirements with respect to ethical conduct and conflicts of interest; providing for public records and meetings; 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 Page 2 of 20

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 state a world-class leader in cancer research and treatment. Further, it is the intent of the Legislature to address the debilitating and deadly effects of Alzheimer's disease by supporting research in Alzheimer's disease statewide through the awarding of research grants on a competitive basis. Additionally, it is the intent of the Legislature to stimulate dramatic economic development, particularly in the biotechnology industry, through investment in this state's biomedical research.

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Section 2. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read:

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20.435 Department of Health; trust funds.--

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(1) The following trust funds are hereby created, to be administered by the Department of Health:

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(h) Biomedical Research Trust Fund.

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1. Funds to be credited to the trust fund shall consist of funds deposited pursuant to ss. s. 215.5601 and 381.922. Funds shall be used for the purposes of the William G. "Bill"

Bankhead, Jr., and David Coley Cancer Research Program and the James and Esther King Biomedical Research Program as specified in ss. 215.5602 and 288.955. The trust fund is exempt from the service charges imposed by s. 215.20.

- 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 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.
- 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 certified by the Governor for up to 3 years following the effective date of the original appropriation.
- 4. The trust fund shall, unless terminated sooner, be terminated on July 1, 2008.
- Section 3. Subsection (3) of section 215.5602, Florida Statutes, is amended, and subsections (11) and (12) are added to that section, to read:

215.5602 James and Esther King Biomedical Research Program.--

- (3) There is created within the Department of Health the Biomedical Research Advisory Council.
- (a) The council shall consist of <u>eleven</u> nine members, including: the chief executive officer of the Florida Division of the American Cancer Society, or a designee; the chief executive officer of the Florida/Puerto Rico Affiliate of the American Heart Association, or a designee; and the chief executive officer of the American Lung Association of Florida, or a designee. The Governor shall appoint the remaining <u>eight</u> six members of the council shall be appointed, as follows:
- 1. The Governor shall appoint four members, two members with expertise in the field of biomedical research, one member from a research university in the state, and one member representing the general population of the state.
- 2. The President of the Senate shall appoint two members, one member with expertise in the field of behavioral or social research and one representative from a cancer program approved by the American College of Surgeons.
- 3. The Speaker of the House of Representatives shall appoint two members, one member from a professional medical organization and one representative from a cancer program approved by the American College of Surgeons.
  - 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 council shall award grants for cancer research through the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program created in s. 381.922.
- (12) The Legislature may annually appropriate funds to the James and Esther King Biomedical Research Program for the purposes of this section.
- Section 4. All appointments to the Biomedical Research

  Advisory Council for the James and Esther King Biomedical

  Research Program which were not made in accordance with s.

  215.5602, Florida Statutes, as amended by this act, shall expire

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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 5. Subsection (5) of section 381.855, Florida Statutes, is amended, and subsections (6), (7), and (8) are added to that section, to read:

- 381.855 Florida Center for Universal Research to Eradicate Disease.--
- (5) There is established within the center an advisory council that shall meet at least annually.
- (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 Secretary of Health from a different institution each term, and the members of the board of directors of the Florida Research Consortium and at least one representative from and appointed by each of the following entities:
  - 1. The Emerging Technology Commission.
  - 1.<del>2.</del> Enterprise Florida, Inc.
- 184 2.<del>3.</del> BioFlorida.

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- 185 3.4. The Biomedical Research Advisory Council.
- 186 4.<del>5.</del> The Florida Medical Foundation.
- 187 5.6. Pharmaceutical Research and Manufacturers of America.
- 188 7. The Florida Tri Agency Coalition on Smoking OR Health.
- 189 6.8. The Florida Cancer Council.
- 190  $\frac{7.9}{}$  The American Cancer Society, Florida Division, Inc.

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191 8.<del>10.</del> The American Heart Association.

- 9.<del>11.</del> The American Lung Association of Florida.
- 193 <u>10.12.</u> The American Diabetes Association, South Coastal Region.
- 195 11.<del>13.</del> The Alzheimer's Association.
- 196 12.<del>14.</del> The Epilepsy Foundation.

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- 197 13.<del>15.</del> The National Parkinson Foundation.
- 198 14.<del>16.</del> The Florida Public Health Foundation, Inc.
- 199 <u>15.17.</u> The Florida Research Consortium Scripps Florida or
  200 the entity formed in this state by The Scripps Research
  201 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) The Legislature may annually appropriate funds to the Florida Center for Universal Research to Eradicate Disease for operating costs.

Section 6. All appointments to the advisory council for the Florida Center for Universal Research to Eradicate Disease which were not made in accordance with s. 381.855, 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 7. 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

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researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;

- (e) Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
- (f) Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research. Section 8. Section 381.922, Florida Statutes, is created to read:
- 381.922 William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program.--
- (1) The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, which may be otherwise cited as the "Bankhead-Coley Program," is created within the Department of Health. The purpose of the program shall be to advance progress towards cures for cancer through grants awarded through a peer-reviewed, competitive process pursuant to s. 381.855.
- (2) The program shall provide grants for cancer research to further the search for cures for cancer.
- (a) Emphasis shall be given to the goals enumerated in s. 381.921, as those goals support the advancement of such cures.
- (b) Preference may be given to grant proposals that foster collaborations among institutions, researchers, and community practitioners, as such proposals support the advancement of cures through basic or applied research, including clinical trials involving cancer patients and related networks.
- (3)(a) Applications for funding for cancer research may be submitted by any university or established research institute in

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the state. All qualified investigators in the state, regardless of institutional affiliation, shall have equal access and opportunity to compete for the research funding. Collaborative proposals, including those that advance the program's goals enumerated in subsection (2), may be given preference. Grants shall be awarded by the Secretary of Health, after consultation with the Biomedical Research Advisory Council, on the basis of scientific merit, as determined by an open, competitive peer-review process that ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding:

- 1. Investigator-initiated research grants.
- 2. Institutional research grants.

- 3. Collaborative research grants, including those that advance the finding of cures through basic or applied research.
- (b) In order to ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the Secretary of Health, in consultation with the council, shall appoint a peer-review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.
- (c) The council and the peer-review panel shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest. A member of the council or panel may not participate in any discussion or

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decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement. Meetings of the council and the peer-review panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

- (4) By December 15 of each year, the Department of Health shall submit to the Governor, the President of the Senate, and the Speaker of the House of Representatives a report indicating progress towards the program's mission and making recommendations that further its purpose.
- Section 9. Subsection (1) of section 561.121, Florida Statutes, is amended to read:
  - 561.121 Deposit of revenue.--

- (1) All state funds collected pursuant to ss. 563.05, 564.06, and 565.12 shall be paid into the State Treasury and disbursed in the following manner:
- (a)  $\frac{1}{1}$ . Two percent of monthly collections of the excise taxes on alcoholic beverages established in ss. 563.05, 564.06, and 565.12 shall be deposited into the Alcoholic Beverage and Tobacco Trust Fund to meet the division's appropriation for the state fiscal year.
- 2. Beginning July 1, 2004, there is annually 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,

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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 the university.
- (b) The remainder of the funds collected pursuant to ss. 563.05, 564.06, and 565.12 collection shall be credited to the General Revenue Fund.

Section 10. 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 added to that section, to read:

1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.--

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The State Board of Education shall enter into an agreement for the utilization of the facilities on the campus of the University of South Florida to be known as the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, including all furnishings, equipment, and other chattels used in the operation of those facilities, with a Florida not-for-profit corporation organized solely for the purpose of governing and operating the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute. This not-for-profit corporation, acting as an instrumentality of the state, shall govern and operate the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute in accordance with the terms of the agreement between the State Board of Education and the not-for-profit corporation. The notfor-profit corporation may, with the prior approval of the State Board of Education, create either for-profit or not-for-profit corporate subsidiaries, or both, to fulfill its mission. The not-for-profit corporation and its subsidiaries are authorized to receive, hold, invest, and administer property and any moneys acquired from private, local, state, and federal sources, as well as technical and professional income generated or derived from practice activities of the institute, for the benefit of the institute and the fulfillment of its mission.

(b)  $\frac{1}{1}$ . The affairs of the not-for-profit corporation shall be managed by a board of directors who shall serve without compensation. The 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,  $\frac{1}{1}$  five  $\frac{1}{1}$  representatives of the state universities, and  $\frac{1}{1}$  no  $\frac{1}{1}$  fewer

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

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(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.

(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

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review process that ensures objectivity, consistency, and high
quality. The following types of applications shall be considered
for funding:

- 1. Investigator-initiated research grants.
- 2. Institutional research grants.

- appropriate and are evaluated fairly on the basis of scientific merit, the board of directors of the not-for-profit corporation, in consultation with the council of scientific advisors, shall appoint a peer review panel of independent, scientifically qualified individuals to review the scientific content of each proposal and establish its scientific priority score. The priority scores shall be forwarded to the council and must be considered in determining which proposals shall be recommended for funding.
- (c) The council of scientific advisors 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 and confidentiality which shall comply with National Institutes of Health standards. All employees, members of the board of directors, and affiliates of the not-for-profit corporation shall follow the same rigorous guidelines for ethical conduct and shall adhere to the same strict policy with regard to conflict of interest and confidentiality. A member of the council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the

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member has entered into a contractual arrangement. Meetings of the council and the peer review panels are subject to chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

(12) The Legislature may annually appropriate funds to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida for the purposes of this section.

Section 11. All appointments to the board of directors of the not-for-profit corporation for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute that were not made in accordance with s. 1004.445, 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 12. (1) The sum of \$6 million is appropriated from the General Revenue Fund to the Biomedical Research Trust Fund in the Department of Health for fiscal year 2006-2007 for purposes of the James and Esther King Biomedical Research Program pursuant to s. 215.5602, Florida Statutes. From these funds up to \$250,000 shall be available for the operating costs of the Florida Center for Universal Research to Eradicate Disease.

(2) The sum of \$9 million is appropriated from 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 for the 2006-2007 fiscal year, and shall be distributed pursuant to s. 381.922, Florida Statutes, to provide grants to researchers

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seeking cures for cancer, with emphasis given to the goals
enumerated in s. 381.921, Florida Statutes. From the total funds
appropriated, an amount of up to 10 percent may be used for
administrative expenses.

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 fiscal year 2006-2007 for the purposes of conducting research, developing and operating integrated data projects, and providing assistance to memory disorder clinics as provided under s. 430.502, Florida Statutes.

Not less than 80 percent of these funds shall be distributed by the center as institutional research grants or investigator-initiated research grants.

Section 13. 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.