

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 7079 PCB HCC 07-10 biomedical research funding
SPONSOR(S): Policy & Budget Council and Representative Bean
TIED BILLS: **IDEN./SIM. BILLS:**

| REFERENCE | ACTION | ANALYST | STAFF DIRECTOR |
|--|-------------------------|----------------|----------------|
| <u>Orig. Comm.: Healthcare Council</u> | <u>13 Y, 0 N</u> | <u>Gormley</u> | <u>Gormley</u> |
| <u>1) Policy & Budget Council</u> | <u>23 Y, 2 N, As CS</u> | <u>Leznoff</u> | <u>Hansen</u> |
| <u>2)</u> | <u></u> | <u></u> | <u></u> |
| <u>3)</u> | <u></u> | <u></u> | <u></u> |
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| <u>5)</u> | <u></u> | <u></u> | <u></u> |

SUMMARY ANALYSIS

This bill amends the James and Esther King Biomedical Research Program to consolidate processes for awarding funds appropriated by the Legislature for biomedical research. To accomplish this purpose, the bill revises provisions relating to funding and broadens the long-term goals of the program. The bill also increases the membership of the Biomedical Research Advisory Council from 11 to 36 members and provides that the council serve as the exclusive source of state funding for biomedical research. The bill requires the establishment of certain committees and revises the duties of the council. The bill deletes requirements for other entities to establish and implement grant funding programs. The bill requires that all biomedical research activities be consolidated under the James and Esther King Biomedical Research Program.

The bill repeals, as of June 30, 2008, the statutory requirements to allocate \$6 million to the Biomedical Research Trust Fund for the James and Esther King Biomedical Research Program; \$9 million to the Biomedical Research Trust Fund for the William G. "Bill" Bankhead Jr. and the David Coley Cancer Research Program; and \$15 million to the Grants and Donations Trust Fund for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

The bill requires, beginning in fiscal year 2008-2009, the annual appropriation of \$5 million in recurring funds from the General Revenue Fund for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute to develop and operate integrated data projects and provide assistance to memory disorder clinics.

In addition, the bill requires, beginning in fiscal year 2008-2009, the annual appropriation of \$5 million and \$2 million in recurring funds from the General Revenue Fund for Bankhead-Coley Cancer Research Grants and Johnnie B. Byrd, Sr., Alzheimer's Grants, respectively.

Last, the bill repeals, on June 30, 2008, the allocation of funds from the Brain and Spinal Cord Injury Program Trust Fund to the University of Florida and the University of Miami for spinal cord injury and brain injury research.

The effective date of the bill is July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

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

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Florida Statutes define at least nine different programs with some responsibility for making or recommending the award of biomedical research grants.¹ Five other state authorized corporations, commissions, and councils are charged with various responsibilities for conducting or otherwise stimulating research programs in the state.² Another 16 advisory groups and councils are given statutory responsibilities for programs involving medical research.³ Although connected by a common theme and purpose, these various programs operate independently, sometimes redundantly to focus on selected diseases, narrowly defined objectives, and single-purpose initiatives.

In several of these cases, the legislation provides for annual allocations of state general revenue funds to be used for developing research capabilities or awarding research grants.⁴ Annual funding based in statute includes \$9.5 million annually is appropriated to the James and Esther King Biomedical Research Program; \$9 million to the William G. Bankhead and David Coley Cancer Research Program; and \$15 million to the Johnny B. Byrd, Sr. Alzheimer's Institute.⁵ Additional funds for research may be allocated through the General Appropriations Act or raised by other means and awarded through various procedures by numerous state-authorized entities.

Effect of Proposed Changes

Generally, the bill amends the James and Esther King Biomedical Research Program to consolidate processes for awarding funds appropriated by the Legislature for biomedical research. To accomplish this purpose, the bill revises provisions relating to funding and broadens the long-term goals of the program. The bill also amends the membership requirements of the Biomedical Research Advisory

¹ See ss. 215.5601 (Lawton Chiles Endowment Fund); 215.5602 (James and Esther King Biomedical Research Program); 381.853 (Florida Center for Brain Tumor Research); 381.855 (Florida Center for Universal Research to Eradicate Disease); 381.92 (Florida Cancer Council); 381.922 (William G. "Bill" Bankhead, Jr., and David Coley Cancer research Program); 430.501 (Alzheimer's Disease Advisory Council); 1004.445 (Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute); and 1004.435, F.S. (Cancer Control and Research Advisory Council).

² See ss. 288.955 (Scripps Florida Funding Corporation); 318.85 (Florida Biomedical and Social Research); 381.0404 (Center for Health Technologies); 1004.226 (The 21st Century Technology, Research, and Scholarship Enhancement Act); and 381.98, F.S. (Florida Public Health Foundation, Inc.).

³ See ss. 385.210 (Arthritis Prevention Education); 385.203 (Diabetes Advisory Council); 385.202 (Statewide Cancer Registry Program); 385.103 (Chronic Disease Community Intervention Program); 381.981 (Health Awareness Campaigns); 381.93 (Mary Brogan Breast and Cervical Cancer Early Detection Program); 381.912 (Cervical Cancer Elimination Task Force); 381.911 (Prostate Cancer Awareness Program); 381.91 (Jessie Trice Cancer Prevention Program); 381.87 (Osteoporosis Prevention and Education Program); 381.04015 (Women's Health Strategy); 381.0032 (Epidemiological Research); 381.0271 (Florida Patient Safety Corporation); 381.0046 (Statewide HIV and AIDS Prevention Program); 430.502 (Alzheimer's Disease Memory Disorder Clinics); and 381.00325, F.S. (Hepatitis Awareness Program).

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

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

Council and provides that the council serve as the exclusive source of state funding for biomedical research.

In addition, the bill requires establishment of certain committees and revises duties of the council. The bill deletes requirements for other entities to establish and implement grant funding programs and revises or repeals other sections of statute in order to conform to the consolidation of these activities under the James and Esther King Biomedical Research Program.

Specifically, the bill:

- Revises the long-term goals of the James and Esther King Biomedical Research Program to include, among other goals, facilitating communication amongst researchers and providers; coordinating, improving, expanding, and monitoring all biomedical research programs within the state; holding periodic biomedical technology summits; and encouraging clinical trials in this state.
- Increases the membership of the Biomedical Research Advisory Council from 11 to 36 members. The new members include the Secretary of the Department of Health; the chief executive officer of Enterprise Florida, Inc.; the chief executive officer of the H. Lee Moffitt Cancer Center; the director of the University of Florida Shands Cancer Center; the chief executive officer of the University of Miami Sylvester Comprehensive Cancer Center; the chief executive officer of the Mayo Clinic, Jacksonville; the president of the Florida Society of Clinical Oncology; and the chief executive officer of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute. In addition, the bill provides nine additional appointments for the Governor and four additional appointments for the President of the Senate and the Speaker of the House of Representatives.
- Revises the advisory nature of the Biomedical Research Advisory Council, authorizing the Council to direct the biomedical research program, establish priorities, conduct program evaluations, and develop guidelines. In addition, the Council must maintain a website with links to peer-reviewed biomedical research. Last, the Council must disseminate breakthroughs in innovative biomedical research and clinical trials.
- Requires the Biomedical Research Advisory Council to establish committees for the following diseases: tobacco-related diseases; cancer; stroke; cardiovascular disease; pulmonary disease; diabetes; autoimmune disorders; Alzheimer's disease; Parkinson's disease; and neurological disorders.
- Requires the Johnnie B. Byrd, Sr., Committee on Alzheimer's Disease to be composed of the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute. The committee's recommendations to the Biomedical Research and Advisory Council must be developed in consultation with the institute's council of scientific advisers.
- Requires the Biomedical Research Advisory Council to, consistent with its new authority to direct the program, starting in 2008, provide to the Legislature a priority list of biomedical research projects.
- Authorizes, in order to provide for grants up to 5 years in length, any balance of any appropriation from the Biomedical Research Trust Fund that is not disbursed but which is obligated pursuant to contract or committed to be expended to be carried forward for up to 5 years following the effective date of the original appropriation.
- Requires any program, board, commission, council, advisory group, or committee created in state law that currently awards, intends to award, or recommends the award of, biomedical research grants, from state funds to, for Fiscal Year 2008-2009 and thereafter, apply for grants or make recommendations to the Biomedical Research Advisory Council.
- Requires the Biomedical Research Advisory Council to take several factors into consideration when prioritizing grant awards, specifically including applications that have the most profound impact on the most deadly and widespread diseases and applications propose the best and most efficient use of state funds.
- Creates a "William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Council" within the Department of Health to "make the state a center of excellence for cancer research." The goals of the Council include expanding cancer research capacity; improving both research and

treatment through greater participation in clinical trials; and reducing the impact of cancer on disparate groups.

- Revises the duties of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute, repealing, on June 30, 2008, the authority of the Center to provide research grants.
- Repeals the Florida Center for Universal Research to Eradicate Disease and the Florida Cancer Council.

C. SECTION DIRECTORY:

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

Section 2. Amends s. 215.5601, F.S., relating to the Lawton Chiles Endowment Fund.

Section 3. Amends s. 215.5602, F.S., relating to the James and Esther King Biomedical Research Program.

Section 4. Amends s. 381.79, F.S., relating to the Brain and Spinal Cord Injury Program Trust Fund.

Section 5. Amends s. 381.853, F.S., relating to the Florida Center for Brain Tumor Research.

Section 6. Amends s. 381.912, F.S., relating to the Cervical Cancer Elimination Task Force.

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

Section 8. Creates s. 381.923, F.S., relating to the Bankhead-Coley Cancer Council.

Section 9. Amends s. 381.98, F.S., relating to the Public Health Foundation, Inc.

Section 10. Amends s. 430.501, F.S., relating to the Alzheimer's Disease Advisory Committee.

Section 11. Amends s. 1004.445, F.S., relating to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

Section 12. Repeals ss. 381.855, 381.92, and 381.921, F.S., relating to the Florida Center for Universal Research to Eradicate Disease and the Florida Cancer Council, respectively.

Section 13. Provides for severability if any provision of the act is held invalid.

Section 14. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill repeals, as of June 30, 2008, the statutory requirements to allocate \$6 million to the Biomedical Research Trust Fund for the James and Esther King Biomedical Research Program; \$9 million to the Biomedical Research Trust Fund for the William G. "Bill" Bankhead Jr. and the David Coley Cancer Research Program; and \$15 million to the Grants and Donations Trust Fund for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.

The bill requires, beginning in fiscal year 2008-2009, the annual appropriation of \$5 million in recurring funds from the General Revenue Fund for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute to develop and operate integrated data projects and provide assistance to memory disorder clinics.

In addition, the bill requires, beginning in fiscal year 2008-2009, the annual appropriation of \$5 million and \$2 million in recurring funds from the General Revenue Fund for Bankhead-Coley Cancer Research Grants and Johnnie B. Byrd, Sr., Alzheimer's Grants, respectively.

Last, the bill repeals, on June 30, 2008, the allocation of funds from the Brain and Spinal Cord Injury Program Trust Fund to the University of Florida and the University of Miami for spinal cord injury and brain injury research.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Consolidation of process for awarding state funds for biomedical research will make it easier for researchers, including those in the private sector, to identify and apply for available funding.

D. FISCAL COMMENTS:

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

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

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On March 20, 2007, the Healthcare Council reported the Proposed Council Bill favorably after the adoption of one amendment. The amendment:

- Creates additional legislative intent regarding the James and Esther King Biomedical Research Program, noting in particular that the biomedical technology sector is a “high impact sector,” having high important to the state’s economy.
- Revises the long-term goals of the James and Esther King Biomedical Research Program to include, among other goals, facilitating communication amongst researchers and providers; coordinating, improving, expanding, and monitoring all biomedical research programs within the state; holding periodic biomedical technology summits; and encouraging clinical trials in this state.
- Increases the membership of the Biomedical Research Advisory Council from 29 to 36 members. The new members include the Secretary of the Department of Health; four additional appointments for the Governor; and one additional appointment for the President of the Senate and the Speaker of the House of Representatives.
- States that, beginning July 1, 2008, the Biomedical Research Advisory Council is the exclusive source of awarding or recommending grants or fellowships in biomedical research, when using state funds.
- Revises the advisory nature of the Biomedical Research Advisory Council, authorizing the Council to direct the biomedical research program, establish priorities, conduct program evaluations, and develop guidelines. In addition, the Council must monitor the supply and demand needs of researchers related to stem cell research and must maintain a website with links to peer-reviewed biomedical research. Last, the Council must disseminate breakthroughs in innovative biomedical research and clinical trials.
- Requires the Biomedical Research Advisory Council to, starting in 2008, provide to the Legislature a priority list of biomedical research projects.
- Requires any program, board, commission council, advisory group, or committee created in state law that currently awards, intends to award, or recommends the award of, biomedical research grants, from state funds to, for Fiscal Year 2008-2009 and thereafter, apply for grants or make recommendations to the Biomedical Research Advisory Council.
- Requires the Biomedical Research Advisory Council to take several factors into consideration when prioritizing grant awards, including applications that have the most profound impact on the most deadly and widespread diseases and applications propose the best and most efficient use of state funds.
- Authorizes the expenditure of up to \$500,000 for the operating costs of the James and Esther King Biomedical Research Program.
- Creates a “William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Council” within the Department of Health to “make the state a center of excellence for cancer research.” The goals of the Council include expanding cancer research capacity; improving both research and treatment through greater participation in clinical trials; and reducing the impact of cancer on disparate groups.
- Revises the duties of the Johnnie B. Byrd, Sr., Alzheimer’s Center and Research Institute, deleting the authority of the Center to provide research grants.
- Deletes, for Fiscal Year 2007-2008 and thereafter, the recurring General Revenue Appropriation to the James and Esther King Biomedical Research Program; the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program; and the Johnnie B. Byrd, Sr., Alzheimer’s Center and Research Institute.
- Repeals the Florida Center for Universal Research to Eradicate Disease and the Florida Cancer Council.

On March 30, 2007, the Policy & Budget Council reported the bill favorably with a Council Substitute. The Council Substitute:

- Authorizes any balance of any appropriation from the Biomedical Research Trust Fund that is not disbursed but which is obligated pursuant to contract or committed to be expended to be carried forward for up to 5 years following the effective date of the original appropriation.
- Adds genetic disorders to the non-exhaustive list of the most deadly and widespread diseases.
- Limits the monitoring of biomedical research in the state to research using state funds.

- Adds the Chief Executive Officer of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute to the Biomedical Research Advisory Council, in lieu of the president of the American College of Surgeons and the chair of the Florida Dialogue on Cancer.
- Adds a representative of the Florida Dialogue on Cancer as an appointee of the Governor.
- Requires the Johnnie B. Byrd, Sr., Committee on Alzheimer's Disease to be composed of the board of directors of the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute. The committee's recommendations to the Biomedical Research and Advisory Council must be developed in consultation with the institute's council of scientific advisers.
- Deletes the requirements that the council monitor the supply and demand needs of researchers relating to stem cell and other types of human tissue research, and that the program is required to maintain such information on its website.
- Requires that the council's priority list to the Legislature be in rank order of priority from the number one priority to the proposal with the lowest priority, including the recommended dollar amount and duration of each proposal.
- Requires the council's rank to be based on the score awarded to the proposal from the peer review panel and the council's determination that the proposal meets the council's requisite determinations.
- Requires the Biomedical Research and Advisory Council, in determining the priority list of biomedical research, to consider the likelihood that the proposed research will result in treatment modalities or technology during the term of the grant or fellowship.
- Specifies that the council's award of grants may occur upon a specific appropriation of the Legislature and that the duration of the grants can be for one to five years.
- Requires that committees also be subject to chapter 119, section 286.011, and s. 24, Art. I of the State Constitution.
- Limits the department's administrative expenses in operating the program to 5 percent of the total funds available.
- Repeals, on June 30, 2008, the appropriation of funds to the University of Florida and the University of Miami for spinal cord injury and brain injury research.
- Repeals, on June 30, 2008, the appropriation of annual, recurring General Revenue Funds for the James and Esther King Biomedical Research Program; the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; and the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute.
- Requires, beginning in fiscal year 2008-2009, the annual appropriation of \$5 million in recurring funds from the General Revenue Fund for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute to develop and operate integrated data projects and provide assistance to memory disorder clinics.
- Requires, beginning in fiscal year 2008-2009, the annual appropriation of \$5 million and \$2 million in recurring funds from the General Revenue Fund for Bankhead-Coley Cancer Research Grants and Johnnie B. Byrd, Sr., Alzheimer's Grants, respectively.
- Requires, beginning in fiscal year 2008-2009, that any grants awarded under the James and Esther King Biomedical Research Program that are not dedicated to cancer or Alzheimer's research be named "James and Esther King Biomedical Research Grants."

The analysis is drafted to the Council Substitute.