CHAPTER 2012-20

Committee Substitute for House Bill No. 655

An act relating to biomedical research; amending s. 20.435, F.S.; extending the period during which certain expenditures may be made from the Biomedical Research Trust Fund; amending s. 215.5602, F.S., relating to James and Esther King Biomedical Research Program; revising the composition, terms, and duties of the Biomedical Research Advisory Council; providing that certain types of applications may, rather than shall, be considered for funding under the program; exempting grant programs under the purview of the council from ch. 120, F.S.; requiring the council to submit a progress report and specifying contents thereof; revising provisions relating to appointment, duties, and meetings of peer review panels; amending s. 381.922, F.S., relating to William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program; revising provisions relating to the awarding of grants; providing that certain types of applications may, rather than shall, be considered for funding under the program; revising provisions relating to appointment, duties, and meetings of peer review panels; removing a requirement for a report to the Governor and the Legislature; amending s. 381.855, F.S., relating to Florida Center for Universal Research to Eradicate Disease; revising composition of an advisory council; providing an effective date.

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

Section 1. Paragraph (c) of subsection (8) of section 20.435, Florida Statutes, is amended to read:

20.435 Department of Health; trust funds.—The following trust funds shall be administered by the Department of Health:

(8) Biomedical Research Trust Fund.

(c) 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 53 years following the effective date of the original appropriation.

Section 2. Paragraph (a) of subsection (3), paragraph (b) of subsection (5), and subsections (4), (6), (7), (9), and (10) of section 215.5602, Florida Statutes, are amended 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.

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(a) The council shall consist of 11 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 remaining 8 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 <u>or from a</u> <u>comprehensive cardiovascular program with experience in biomedical</u> <u>research approved by the American College of Cardiology</u> 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. 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. The first two appointments by the Governor and the first appointment by the President of the Senate and the Speaker of the House of Representatives on or after July 1, 2012, shall be for a term of 2 years.

(4) The council shall advise the State Surgeon General as to the direction and scope of the biomedical research program. The responsibilities of the council may include, but are not limited to:

(a) Providing advice on program priorities and emphases.

(b) Providing advice on the overall program budget.

(c) Participating in periodic program evaluation.

(d) 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) Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials.

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(f) Developing criteria and standards for the award of research grants.

(g) Developing <u>guidelines</u> administrative procedures relating to solicitation, review, and award of research grants and fellowships, to ensure an impartial, high-quality peer review system.

(h) Developing and supervising research peer review panels.

 $(\underline{h})(i)$ Reviewing reports of peer review panels and making recommendations for research grants and fellowships.

 $(\underline{i})(\underline{j})$ Developing and providing oversight regarding mechanisms for the dissemination of research results.

(5)

(b) Grants and fellowships shall be awarded by the State Surgeon General, after consultation with the council, on the basis of scientific merit, as determined by <u>the competitively open peer-reviewed process to</u> <u>ensure an open competitive peer review process that ensures objectivity</u>, consistency, and high quality. The following types of applications <u>may shall</u> be considered for funding:

- 1. Investigator-initiated research grants.
- 2. Institutional research grants.
- 3. Predoctoral and postdoctoral research fellowships.

(6) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the <u>Department of Health</u> State Surgeon General, in consultation with the council, shall appoint a peer review <u>panels panel</u> of independent, scientifically qualified individuals to review the scientific <u>merit content</u> 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.

(7) The council and the peer review <u>panels panel</u> 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 council or <u>a</u> panel may not participate in any discussion or decision <u>of the council or a panel</u> 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 shall be subject to the provisions of chapter 119, s. 286.011, and s. 24, Art. I of the State Constitution.

(9) The grant programs under the purview of the council are exempt from chapter 120 department, after consultation with the council, may adopt rules as necessary to implement this section.

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(10) The council shall submit <u>a fiscal-year</u> an annual progress report on the <u>programs under its purview</u> 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 <u>December 15</u> February 1. The report must include:

(a) A list of 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 peer reviewed journals involving research supported by grants or fellowships awarded under the program.

(d) The <u>state ranking and</u> total amount of biomedical research funding currently flowing into the state <u>from the National Institutes of Health</u>.

(e) New grants for biomedical research which were funded based on research supported by grants or fellowships awarded under the program.

(f) Progress <u>towards programmatic goals, particularly</u> in the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

(g) Recommendations to further the mission of the programs.

Section 3. Subsection (3) and present subsection (4) of section 381.922, Florida Statutes, are amended, and subsection (5) is renumbered as subsection (4) of that section, to read:

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

(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. Grants shall be awarded by the <u>department State Surgeon General</u>, after consultation with the Biomedical Research Advisory Council, on the basis of scientific merit, as determined by <u>the competitively open peer-reviewed process to ensure an</u> open, competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications <u>may shall</u> be considered for funding:

1. Investigator-initiated research grants.

2. Institutional research grants.

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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 <u>department</u> State Surgeon General, in consultation with the council, shall appoint a peer review <u>panels panel</u> of independent, scientifically qualified individuals to review the scientific <u>merit content</u> 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 <u>panels</u> <u>panel</u> 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 decision <u>of the council or a panel</u> 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. <u>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.</u>

(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 4. Paragraph (a) of subsection (5) of section 381.855, Florida Statutes, is amended 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-forprofit 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.
- 3. The Biomedical Research Advisory Council.
- 4. The Florida Medical Foundation.
- 5. Pharmaceutical Research and Manufacturers of America.

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- 6. The American Cancer Society, Florida Division, Inc.
- 7. The American Heart Association, Greater Southeast Affiliate.
- 8. The American Lung Association of Florida.
- 9. The American Diabetes Association, South Coastal Region.
- 10. The Alzheimer's Association.
- 11. The Epilepsy Foundation.
- 12. The National Parkinson Foundation.
- 13. The Florida Public Health Institute, Inc.
- 14. The Florida Research Consortium.
- Section 5. This act shall take effect July 1, 2012.
- Approved by the Governor March 23, 2012.
- Filed in Office Secretary of State March 23, 2012.