1 A bill to be entitled 2 An act relating to biomedical research; amending s. 3 20.435, F.S.; specifying use of funds deposited in the Biomedical Research Trust Fund; revising a time limit 4 5 relating to certain undisbursed balances of appropriations 6 from the trust fund; amending s. 215.5601, F.S.; 7 conforming a cross-reference; amending s. 215.5602, F.S.; 8 revising the purposes and long-term goals of the James and 9 Esther King Biomedical Research Program; providing for certain funds appropriated for the program to be deposited 10 into the Biomedical Research Trust Fund; specifying use of 11 such funds; renaming the Biomedical Research Advisory 12 Council the Biomedical Research Commission; revising 13 membership of the commission; providing that the 14 commission serves as an exclusive source of biomedical 15 16 research grant and fellowship awards; requiring the commission to create committees for specified purposes; 17 requiring the commission to adopt policies and procedures 18 19 regarding the committees and to receive input from outside 20 sources; revising responsibilities of the commission; creating a future requirement for the commission to submit 21 priorities for funding research relating to tobacco-22 related and nontobacco-related diseases to the State 23 24 Surgeon General; requiring the State Surgeon General to 25 provide commission funding priorities to the Legislature; 26 providing restrictions on the State Surgeon General; providing criteria for ranking priorities; authorizing the 27 State Surgeon General to award grants or fellowships; 28 Page 1 of 33

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providing for the award of grants or fellowships upon a 29 30 specific appropriation; prohibiting the funding of research projects not in compliance with the requirements 31 of the section; providing restrictions on the 32 recommendation or award of grants or fellowships by other 33 programs and entities; providing for future reductions of 34 35 limits on annual administrative expenses; revising 36 requirements relating to the commission's annual progress 37 report; providing a future expiration date for the 38 commission to award grants for the Bankhead-Coley Program; revising provisions relating to appropriations; providing 39 for nonapplicability of James and Esther King Biomedical 40 Research Program requirements to specified programs and 41 the use of certain operating funds appropriated to 42 universities; extending the expiration date of the 43 44 program; amending s. 381.79, F.S.; providing for the expiration of a provision relating to the distribution of 45 funds from the Brain and Spinal Cord Injury Program Trust 46 47 Fund; amending s. 381.853, F.S.; providing a requirement 48 for the Florida Center for Brain Tumor Research relating to the use of state funds for biomedical research; 49 amending s. 381.855, F.S.; providing additional program 50 functions for the Florida Center for Universal Research to 51 Eradicate Disease; requiring the center to disseminate 52 53 certain information if an appropriation is made; requiring 54 the center to identify ways to attract students from 55 underserved communities for roles as health professionals and researchers; conforming references to changes made by 56 Page 2 of 33

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57 the act; amending s. 381.911, F.S.; conforming references 58 to changes made by the act; amending s. 381.922, F.S., relating to the William G. "Bill" Bankhead, Jr., and David 59 Coley Cancer Research Program; creating a future 60 requirement for the commission to submit priorities for 61 62 funding cancer research to the State Surgeon General; 63 requiring the State Surgeon General to provide commission 64 funding priorities to the Legislature; providing 65 restrictions on the State Surgeon General; providing criteria for ranking priorities; authorizing the State 66 Surgeon General to award grants; providing for the award 67 of grants upon a specific appropriation; prohibiting the 68 funding of research projects not in compliance with the 69 requirements of the section; conforming references to 70 changes made by the act; revising process and provisions 71 72 relating to future peer review of grant applications to conform to the changes to the biomedical research program 73 made by the act; deleting a provision requiring the 74 75 Division of Statutory Revision within the Office of Legislative Services to certify certain language and 76 citations related to the program; deleting a provision 77 requiring future legislative review of the program; 78 79 revising the expiration date of the program; amending ss. 458.324 and 459.0125, F.S.; conforming references to 80 changes made by the act; amending s. 1004.445, F.S.; 81 82 providing for the future repeal of specified provisions to conform to changes made by the act; reducing 83 appropriations for fiscal year 2008-2009; providing for 84 Page 3 of 33

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85 and specifying use of future appropriations; repealing s. 86 381.0404, F.S., relating to the Center for Health 87 Technologies; repealing s. 381.85, F.S., relating to biomedical and social research; repealing s. 381.912, 88 F.S., relating to the Cervical Cancer Elimination Task 89 Force; repealing s. 381.92, F.S., relating to the Florida 90 91 Cancer Council; repealing s. 381.921, F.S., relating to the Florida Cancer Council; repealing s. 381.98, F.S., 92 93 relating to the Florida Public Health Foundation, Inc.; repealing s. 381.981, F.S., relating to health awareness 94 campaigns; repealing s. 1004.435, F.S., relating to cancer 95 control and research; providing for severability; 96 providing an effective date. 97 98 99 Be It Enacted by the Legislature of the State of Florida: 100 101 Section 1. Paragraph (h) of subsection (1) of section 20.435, Florida Statutes, is amended to read: 102 103 20.435 Department of Health; trust funds.--The following trust funds are hereby created, to be 104 (1)105 administered by the Department of Health: 106 (h) Biomedical Research Trust Fund. Funds to be credited to the trust fund shall consist of 107 1. funds deposited pursuant to s. 215.5601 and any other funds 108 109 appropriated by the Legislature. Funds shall be used for the 110 purposes of the James and Esther King Biomedical Research Program and the William G. "Bill" Bankhead, Jr., and David Coley 111 Cancer Research Program as specified in ss. 215.5602, 288.955, 112 Page 4 of 33

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113	and 381.922. The trust fund is exempt from the service charges
114	imposed by s. 215.20.
115	2. Funds deposited into the trust fund pursuant to s.
116	215.5601 and any other funds appropriated by the Legislature as
117	specified in s. 215.5602(12)(a) for research related to tobacco-
118	related diseases shall be used exclusively for the purpose of
119	awarding grants and fellowships for research regarding the
120	prevention, diagnosis, treatment, and cure of tobacco-related
121	diseases by the James and Esther King Biomedical Research
122	Program.
123	3. Funds deposited into the trust fund pursuant to the
124	William G. "Bill" Bankhead, Jr., and David Coley Cancer Research
125	Program as specified in s. 381.922 shall be used for the purpose
126	of awarding grants for cancer research by the William G. "Bill"
127	Bankhead, Jr., and David Coley Cancer Research Program.
128	4. All other funds deposited into the trust fund shall be
129	used for the purpose of awarding grants and fellowships for
130	biomedical research regarding the prevention, diagnosis,
131	treatment, and cure of the most deadly and widespread
132	nontobacco-related acute, chronic, and degenerative diseases by
133	the James and Esther King Biomedical Research Program as
134	specified in s. 215.5602(2)(b) and (12)(b).
135	5.2. Notwithstanding the provisions of s. 216.301 and
136	pursuant to s. 216.351, any balance in the trust fund at the end
137	of any fiscal year shall remain in the trust fund at the end of
138	the year and shall be available for carrying out the purposes of
139	the trust fund. The department may invest these funds
140	independently through the Chief Financial Officer or may
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141 negotiate a trust agreement with the State Board of
142 Administration for the investment management of any balance in
143 the trust fund.

144 <u>6.3.</u> Notwithstanding s. 216.301 and pursuant to s. 145 216.351, any balance of any appropriation from the Biomedical 146 Research Trust Fund which is not disbursed but which is 147 obligated pursuant to contract or committed to be expended may 148 be carried forward for up to 5 + 3 years following the effective 149 date of the original appropriation.

Section 2. Paragraph (e) of subsection (5) of section215.5601, Florida Statutes, is amended to read:

152

215.5601 Lawton Chiles Endowment Fund.--

153

(5) AVAILABILITY OF FUNDS; USES.--

(e) Notwithstanding s. 216.301 and pursuant to s. 216.351,
all unencumbered balances of appropriations from each
department's respective Tobacco Settlement Trust Fund as of June
30 or undisbursed balances as of December 31 shall revert to the
endowment's principal. Unencumbered balances in the Biomedical
Research Trust Fund shall be managed as provided in s.

160 20.435(1)(h)5.<del>2.</del>

161 Section 3. Section 215.5602, Florida Statutes, is amended 162 to read:

163 215.5602 James and Esther King Biomedical Research
164 Program.--

(1) There is established within the Department of Health
the James and Esther King Biomedical Research Program funded by
the proceeds of the Lawton Chiles Endowment Fund pursuant to s.
215.5601. The purpose of the James and Esther King Biomedical
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169 Research Program is to provide an annual and perpetual source of 170 funding in order to support research initiatives that address 171the health care problems of Floridians in the areas of tobacco-172 related cancer, cardiovascular disease, stroke, and pulmonary 173 disease and nontobacco-related acute, chronic, and degenerative 174 diseases, including cancer, cardiovascular disease, stroke, 175 pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders, including Alzheimer's disease, 176 177 epilepsy, and Parkinson's disease. The long-term goals of the 178 program are to: 179 (a) Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for the most deadly 180 and widespread acute, chronic, and degenerative diseases, 181 182 including, but not limited to, tobacco-related diseases, cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, 183 184 autoimmune and genetic disorders, and neurological disorders, 185 including Alzheimer's disease, epilepsy, and Parkinson's 186 disease. 187 (b) Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of tobacco-188 189 related diseases related to tobacco use, including cancer, 190 cardiovascular disease, stroke, and pulmonary disease. Expand the foundation of biomedical knowledge relating 191 (C) to the prevention, diagnosis, treatment, and cure of the most 192 widespread acute, chronic, and degenerative diseases affecting 193 Floridians, including, but not limited to, cancer, 194 cardiovascular disease, stroke, pulmonary disease, diabetes, 195 autoimmune and genetic disorders, and neurological disorders, 196

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197 including Alzheimer's disease, epilepsy, and Parkinson's
198 disease.

(d) Expand the foundation of biomedical knowledge relating to the deadly and most widespread acute, chronic, and degenerative diseases and identify biomedical solutions regarding health disparities that exist in relation to these diseases.

204 <u>(e) (c)</u> Improve the quality of the state's academic health 205 centers by bringing the advances of biomedical research into the 206 training of physicians and other health care providers.

207 <u>(f)</u> (d) Increase the state's per capita funding for 208 research by undertaking new initiatives in public health and 209 biomedical research that will attract additional funding from 210 outside the state.

211 (g) (e) Stimulate economic activity in the state in areas 212 related to biomedical research, such as the research and 213 production of pharmaceuticals, biotechnology, and medical 214 devices.

215 (2) (a) Funds appropriated for the James and Esther King 216 Biomedical Research Program pursuant to the Lawton Chiles 217 Endowment Fund created in s. 215.5601 and additional funding 218 provided under paragraph (12)(a) for research related to 219 tobacco-related diseases shall be credited to the Biomedical 220 Research Trust Fund pursuant to s. 20.435 and shall be used exclusively for the award of grants and fellowships related to 221 the prevention, diagnosis, treatment, and cure of tobacco-222 related diseases, including cancer, cardiovascular disease, 223 224 stroke, and pulmonary disease and for expenses incurred in the

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225 administration of this section. Priority shall be granted to 226 research designed to prevent or cure tobacco-related diseases. Beginning in fiscal year 2009-2010, and each fiscal 227 (b) 228 year thereafter, all other funds appropriated for the James and 229 Esther King Biomedical Research Program shall be credited to the 230 Biomedical Research Trust Fund pursuant to s. 20.435 and shall 231 be used exclusively for the award of grants and fellowships as established in this section; for research relating to the 232 233 prevention, diagnosis, treatment, and cure of the most deadly and widespread acute, chronic, and degenerative nontobacco-234 235 related diseases affecting Floridians related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary 236 disease, diabetes, autoimmune and genetic disorders, and 237 238 neurological disorders, including Alzheimer's disease, epilepsy, 239 and Parkinson's disease, + and for expenses incurred in the 240 administration of this section. Priority shall be granted to research designed to prevent or cure disease. 241

(3) There is created within the Department of Health the
Biomedical Research <u>Commission</u> Advisory Council.

The commission <del>council</del> shall consist of 15 <del>11</del> members, 244 (a) 245 including: the chief executive officer of the Florida Division 246 of the American Cancer Society, or a designee; the chief 247 executive officer of the Greater Southeast Florida/Puerto Rico Affiliate of the American Heart Association, or a designee; and 248 249 the chief executive officer of the American Lung Association of Florida, or a designee; the chief executive officer of the South 250 Coastal Region of the American Diabetes Association, or a 251 designee; and the president of the Florida Medical Association, 252

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253 <u>or a designee</u>. The remaining <u>10</u> <del>8</del> members of the <u>commission</u> 254 <del>council</del> 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.

259 2. The President of the Senate shall appoint <u>three</u> two 260 members, one member with expertise in the field of behavioral or 261 social research and <u>two members representing volunteer health</u> 262 <u>organizations operating in the state that focus on Alzheimer's</u> 263 <u>disease, Parkinson's disease, epilepsy, stroke, or autoimmune</u> 264 <u>and genetic disorders</u> <del>one representative from a cancer program</del> 265 <del>approved by the American College of Surgeons</del>.

266 The Speaker of the House of Representatives shall 3. 267 appoint three two members, two members representing volunteer 268 health organizations operating in the state that focus on 269 Alzheimer's disease, Parkinson's disease, epilepsy, stroke, or 270 autoimmune and genetic disorders one member from a professional 271 medical organization and one member representing representative from a cancer program approved by the American College of 272 273 Surgeons.

274

In making these appointments, the Governor, the President of the Senate, and the Speaker of the House of Representatives shall select primarily, but not exclusively, Floridians with biomedical and lay expertise in the general areas of cancer, cardiovascular disease, stroke, and pulmonary disease, diabetes, autoimmune and genetic disorders, and neurological disorders,

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281 <u>including Alzheimer's disease, epilepsy, and Parkinson's</u> 282 <u>disease</u>. The appointments shall be for a 3-year term and shall 283 reflect the diversity of the state's population. An appointed 284 member may not serve more than two consecutive terms.

285 Except for the William G. "Bill" Bankhead, Jr., and (b) 286 David Coley Cancer Research Program that expires June 30, 2011, 287 pursuant to s. 381.922, beginning in fiscal year 2009-2010, and each fiscal year thereafter, funds appropriated for the James 288 289 and Esther King Biomedical Research Program shall serve as the 290 exclusive source of awarding grants or fellowships for 291 biomedical research in the state using state funds. This 292 paragraph does not preclude another grant or fellowship program created by state law from awarding grants from funds received 293 294 from private or federal sources if permitted by state law.

(c) The commission shall create committees to focus on
 disease-specific areas, including, but not limited to, tobacco related diseases, cancer, stroke, cardiovascular disease,
 pulmonary disease, diabetes, autoimmune and genetic disorders,
 and neurological disorders, including Alzheimer's disease,
 epilepsy, and Parkinson's disease.

301 (d) (b) The commission council shall adopt internal 302 organizational procedures as necessary for its efficient 303 organization, including policies and procedures regarding the 304 creation and composition of the committees, the submission of reports and recommendations by committees regarding the awarding 305 of grants and fellowships, coordination between the commission 306 and committees, and the methods for receiving input from 307 308 individuals, organizations, or entities that are not members of

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309 the commission or its committees regarding the prioritization of 310 research. (e) (c) The department shall provide such staff, 311 information, and other assistance as is reasonably necessary to 312 313 assist the commission council in carrying out its 314 responsibilities, including those of its committees. 315 (f) (d) Members of the commission council shall serve 316 without compensation, but may receive reimbursement as provided 317 in s. 112.061 for travel and other necessary expenses incurred in the performance of their official duties, including attending 318 committee meetings. 319 320 (4)The commission council shall, after considering the recommendations of its committees, advise the State Surgeon 321 322 General as to the direction and scope of the biomedical research program. The responsibilities of the commission council may 323 324 include, but are not limited to: 325 Establishing Providing advice on program priorities (a) 326 and emphases. 327 (b) Evaluating Providing advice on the overall program budget and making recommendations to the State Surgeon General 328 329 and the Legislature regarding future appropriations. 330 (C) Participating in periodic program evaluation. (d) Developing Assisting in the development of quidelines 331 to ensure fairness, neutrality, and adherence to the principles 332 of merit and quality in the conduct of the program. 333 Developing Assisting in the development of appropriate 334 (e) linkages to nonacademic entities, such as voluntary 335

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336 organizations, health care delivery institutions, industry,337 government agencies, and public officials.

338 (f) Developing criteria and standards for the award of339 research grants.

340 (g) Developing administrative procedures relating to
341 solicitation, <u>independent peer</u> review, and award of research
342 grants and fellowships, to ensure an impartial, high-quality,
343 science-based peer review system.

344 (h) Developing and supervising research peer review345 panels.

346 (i) Reviewing reports of peer review panels and making347 recommendations for research grants and fellowships.

348 (j) Developing and providing oversight regarding349 mechanisms for the dissemination of research results.

(5) (a) Applications for biomedical research funding under the program may be submitted from any university or established research institute in the state. All qualified investigators in the state, regardless of institution affiliation, shall have equal access and opportunity to compete for the research funding.

(b) <u>Beginning in fiscal year 2008-2009</u>, grants and fellowships shall be awarded by the State Surgeon General, after consultation with the <u>commission</u> <del>council</del>, on the basis of scientific merit, as determined by an open competitive peer review process that ensures objectivity, consistency, and high quality.

362 (c) Beginning in fiscal year 2009-2010, and each fiscal 363 year thereafter, the State Surgeon General shall submit to the Page 13 of 33

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364	Legislature by February 1 priority lists for the funding of both
365	tobacco-related and nontobacco-related biomedical research by
366	the Legislature based on the recommendations made by the
367	commission after peer review and scoring of the applications
368	received. Recommendations to the Legislature shall be in the
369	form of lists submitted by the State Surgeon General of the
370	commission's rank order of priority from the proposal with the
371	highest priority through the proposal with the lowest priority,
372	including the recommended dollar amount and duration for each
373	proposal. The State Surgeon General may not reject or modify the
374	commission's recommendations. Successful applicants shall be
374	awarded grants or fellowships by the State Surgeon General based
376	upon the recommendations of the commission and the final funding
377	decision made by the Legislature. Funding for grant and
378	fellowship applications for tobacco-related research shall be
379	based upon funds available pursuant to paragraphs (2)(a) and
380	(12)(a) and s. 215.5601.
381	(d) Beginning in fiscal year 2009-2010, and each fiscal
382	year thereafter, the commission's overall ranking of grant and
383	fellowship applications shall be based on the score awarded to
384	the proposal by peer reviewers on the basis of scientific merit
385	through an open competitive peer review process that ensures
386	objectivity, consistency, and high quality and the commission's
387	determination of the following:
388	1. The projected impact that the proposed research will
389	have on the most deadly and widespread diseases affecting
390	Floridians at the time the grant or fellowship is awarded;

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391	2. The likelihood or possibility that the proposed
392	research will result in new treatment modalities or technology
393	during the term of the grant or fellowship; and
394	3. Whether the research proposed offers an efficient use
395	of state funds in order to prevent or cure disease.
396	(e) The following types of applications shall be
397	considered for funding:
398	1. Investigator-initiated research grants.
399	2. Institutional research grants.
400	3. Predoctoral and postdoctoral research fellowships.
401	(f) The State Surgeon General shall award grants or
402	fellowships for terms of 1 to 5 years. State funds shall only be
403	provided for research that was applied for, reviewed, and
404	recommended in accordance with this section.
405	(g) Except for the William G. "Bill" Bankhead, Jr., and
406	David Coley Cancer Research Program that expires June 30, 2011,
407	pursuant to s. 381.922, beginning July 1, 2009, and each fiscal
408	year thereafter, any program, board, commission, council,
409	advisory group, agency, or entity created by state law that
410	awards or recommends the award of grants or fellowships for
411	biomedical research may not award grants or fellowships that
412	require the use of state funds and, instead, shall make any
413	recommendation to the commission and its committees for the
414	prioritization and award of grants and fellowships through the
415	James and Esther King Biomedical Research Program.
416	(6) To ensure that all proposals for research funding are
417	appropriate and are evaluated fairly on the basis of scientific
418	merit, the State Surgeon General, in consultation with the
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419 <u>commission</u> <del>council</del>, shall appoint a peer review panel of 420 independent, scientifically qualified individuals to review the 421 scientific content of each proposal and establish its scientific 422 priority score. The priority scores shall be forwarded to the 423 <u>commission and its committees</u> <del>council</del> and must be considered in 424 determining which proposals shall be recommended for funding.

425 (7) The commission, the committees, council and the peer review panel shall establish and follow rigorous guidelines for 426 427 ethical conduct and adhere to a strict policy with regard to conflict of interest. A member of the commission, committee, 428 429 council or panel may not participate in any discussion or decision with respect to a research proposal by any firm, 430 entity, or agency with which the member is associated as a 431 432 member of the governing body or as an employee, or with which 433 the member has entered into a contractual arrangement. Meetings 434 of the commission, committees, council and the peer review panels shall be subject to the provisions of chapter 119, s. 435 436 286.011, and s. 24, Art. I of the State Constitution.

437 (8) The department may contract on a competitive-bid basis with an appropriate entity to administer the program. 438 439 Administrative expenses may not exceed 15 percent of the total 440 funds available to the program in any given year. Effective July 1, 2009, administrative expenses may not exceed 10 percent of 441 the total funds available to the program in any given year. 442 Effective July 1, 2011, administrative expenses may not exceed 5 443 444 percent of the total funds available to the program in any given 445 year.

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(9) The department, after consultation with the <u>commission</u>
council, may adopt rules <u>pursuant to ss. 120.536(1) and 120.54</u>
as necessary to implement this section.

449 In addition to its recommendations regarding (10)appropriations for the award of grants and fellowships to the 450 State Surgeon General and the Legislature, the commission 451 452 council shall submit an annual progress report on the state of 453 biomedical research in this state to the Florida Center for 454 Universal Research to Eradicate Disease and to the Governor, the 455 State Surgeon General, the President of the Senate, and the 456 Speaker of the House of Representatives by February 1. The 457 report must include:

(a) A list of <u>current</u> research projects supported bygrants or fellowships awarded under the program.

460

(b) A list of recipients of program grants or fellowships.

(c) A list of publications in <u>peer-reviewed</u> peer reviewed
journals involving research supported by grants or fellowships
awarded under the program.

(d) The total amount of biomedical research fundingcurrently flowing into the state.

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

(f) Progress in the prevention, diagnosis, treatment, and cure of the most deadly and widespread acute, chronic, and degenerative tobacco-related and nontobacco-related diseases affecting Floridians diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease, Page 17 of 33

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# 474 <u>diabetes, autoimmune and genetic disorders, and neurological</u> 475 <u>disorders, including Alzheimer's disease, epilepsy, and</u> 476 <u>Parkinson's disease</u>.

(11) The <u>commission</u> <del>council</del> shall award grants for cancer
research through the William G. "Bill" Bankhead, Jr., and David
Coley Cancer Research Program created in s. 381.922. <u>This</u>
subsection expires June 30, 2011.

(12)(a) Beginning in fiscal year 2006-2007, the sum of \$6 481 million is appropriated annually from recurring funds in the 482 General Revenue Fund to the Biomedical Research Trust Fund 483 484 within the Department of Health for purposes of the award of grants and fellowships by the James and Esther King Biomedical 485 Research Program for research relating to tobacco-related 486 487 diseases pursuant to this section. From these funds up to 488 \$250,000 shall be available for the operating costs of the 489 Florida Center for Universal Research to Eradicate Disease.

490 Beginning in fiscal year 2009-2010, and each fiscal (b) 491 year thereafter, the Legislature may appropriate funds from 492 recurring funds in the General Revenue Fund to the Biomedical 493 Research Trust Fund within the Department of Health for purposes 494 of the award of grants and fellowships by the James and Esther 495 King Biomedical Research Program for research of the most deadly and widespread nontobacco-related acute, chronic, and 496 497 degenerative diseases pursuant to this section. Any research grant or fellowship awarded for Alzheimer's research pursuant to 498 this section shall be named a "Johnnie B. Byrd, Sr. Alzheimer's 499 Grant." Any research grant or fellowship awarded for cancer 500

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501 research pursuant to this section shall be named a "Bankhead-502 Coley Cancer Grant."

503 (13) This section does not apply to the 21st Century World
 504 Class Scholars, Centers of Excellence, or State University
 505 Research Commercialization Assistance Grant Programs established
 506 under s. 1004.226; to the University Major Gifts Program
 507 established under s. 1011.94; or to the use of general operating
 508 funds appropriated to universities.

509 <u>(14)</u> (13) By June 1, 2014 2009, the Division of Statutory 510 Revision of the Office of Legislative Services shall certify to 511 the President of the Senate and the Speaker of the House of 512 Representatives the language and statutory citation of this 513 section, which is scheduled to expire January 1, 2016 2011.

514 <u>(15)(14)</u> The Legislature shall review the performance, the 515 outcomes, and the financial management of the James and Esther 516 King Biomedical Research Program during the <u>2015</u> <del>2010</del> Regular 517 Session of the Legislature and shall determine the most 518 appropriate funding source and means of funding the program 519 based on its review.

520 (16)(15) This section expires January 1, 2016 2011, unless 521 reviewed and reenacted by the Legislature before that date.

522 Section 4. Subsection (3) of section 381.79, Florida 523 Statutes, is amended to read:

524

381.79 Brain and Spinal Cord Injury Program Trust Fund.--

(3) Annually, 5 percent of the revenues deposited monthly
in the fund pursuant to s. 318.21(2)(d) shall be appropriated to
the University of Florida and 5 percent to the University of
Miami for spinal cord injury and brain injury research. The

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529	amount to be distributed to the universities shall be calculated
530	based on the deposits into the fund for each quarter in the
531	fiscal year, but may not exceed \$500,000 per university per
532	year. Funds distributed under this subsection shall be made in
533	quarterly payments at the end of each quarter during the fiscal
534	year. This subsection expires June 30, 2009.
535	Section 5. Paragraph (h) is added to subsection (4) of
536	section 381.853, Florida Statutes, to read:
537	381.853 Florida Center for Brain Tumor Research
538	(4) The Florida Center for Brain Tumor Research is
539	established within the Evelyn F. and William L. McKnight Brain
540	Institute of the University of Florida.
541	(h) Beginning in fiscal year 2009-2010, and each fiscal
542	year thereafter, if the center seeks to conduct biomedical
543	research using state funds, the center shall apply for funding
544	through the James and Esther King Biomedical Research Program
545	pursuant to s. 215.5602.
546	Section 6. Paragraph (a) of subsection (5) of section
547	381.855, Florida Statutes, is amended, and paragraphs (n), (o),
548	(p), and (q) are added to subsection (3) of that section, to
549	read:
550	381.855 Florida Center for Universal Research to Eradicate
551	Disease
552	(3) There is established within the Department of Health
553	the Florida Center for Universal Research to Eradicate Disease,
554	which shall be known as "CURED."

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555	(n) The center shall identify ways to attract new research
556	talent and attendant national grant producing researchers to
557	research facilities in this state.
558	(o) If funds are specifically appropriated by the
559	Legislature, the center shall disseminate information to
560	Floridians and treatment providers about specified diseases and
561	conditions and available methods of preventing, diagnosing,
562	treating, and curing those diseases and conditions.
563	(p) The center shall provide information regarding
564	research needs in the state to the Biomedical Research
565	Commission located in the James and Esther King Biomedical
566	Research Program.
567	(q) The center shall identify ways to attract students
568	from underserved communities for roles as health professionals
569	and researchers.
570	(5) There is established within the center an advisory
571	council that shall meet at least annually.
572	(a) The council shall consist of one representative from a
573	Florida not-for-profit institution engaged in basic and clinical
574	biomedical research and education which receives more than \$10
575	million in annual grant funding from the National Institutes of
576	Health, to be appointed by the State Surgeon General from a
577	different institution each term, and one representative from and
578	appointed by each of the following entities:
579	1. Enterprise Florida, Inc.
580	2. BioFlorida.
581	3. The Biomedical Research Commission Advisory Council.
582	4. The Florida Medical Foundation.
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583	5. Pharmaceutical Research and Manufacturers of America.
584	6. The Florida Cancer Council.
585	
586	7.8. The American Heart Association.
587	<u>8.9.</u> The American Lung Association of Florida.
588	<u>9.10.</u> The American Diabetes Association, South Coastal
589	Region.
590	<u>10.11.</u> The Alzheimer's Association.
591	<u>11.<del>12.</del></u> The Epilepsy Foundation.
592	<u>12.<del>13.</del> The National Parkinson Foundation.</u>
593	14. The Florida Public Health Foundation, Inc.
594	<u>13.</u> The Florida Research Consortium.
595	Section 7. Subsections (2), (3), and (4) of section
596	381.911, Florida Statutes, are amended to read:
597	381.911 Prostate Cancer Awareness Program
598	(2) For purposes of implementing the program, the
599	Department of Health and the Florida Public Health Foundation,
600	<del>Inc.,</del> may:
601	(a) Conduct activities directly or enter into a contract
602	with a qualified nonprofit community education entity.
603	(b) Seek any available gifts, grants, or funds from the
604	state, the Federal Government, philanthropic foundations, and
605	industry or business groups.
606	(3) A prostate cancer advisory committee is created to
607	advise and assist the Department of Health <del>and the Florida</del>
608	Public Health Foundation, Inc., in implementing the program.
609	(a) The State Surgeon General shall appoint the advisory
610	committee members, who shall consist of:
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611 1. Three persons from prostate cancer survivor groups or612 cancer-related advocacy groups.

613 2. Three persons who are scientists or clinicians from614 public universities or research organizations.

3. Three persons who are engaged in the practice of a
cancer-related medical specialty from health organizations
committed to cancer research and control.

(b) Members shall serve without compensation but are
entitled to reimbursement, pursuant to s. 112.061, for per diem
and travel expenses incurred in the performance of their
official duties.

622 (4) The program shall coordinate its efforts with those of
623 the Florida Public Health Foundation, Inc.

624 Section 8. Section 381.922, Florida Statutes, is amended 625 to read:

381.922 William G. "Bill" Bankhead, Jr., and David ColeyCancer 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 peerreviewed, competitive process.

(2) The program shall provide grants for cancer researchto further the search for cures for cancer.

(a) Emphasis shall be given to the goals <u>that</u> enumerated
 637 in s. 381.921, as those goals support the advancement of such
 638 cures.

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(b) Preference may be given to grant proposals that foster
collaborations among institutions, researchers, and community
practitioners, as such proposals support the advancement of
cures through basic or applied research, including clinical
trials involving cancer patients and related networks.

(3) (a) Applications for funding for cancer research may be
submitted by any university or established research institute in
the state. All qualified investigators in the state, regardless
of institutional affiliation, shall have equal access and
opportunity to compete for the research funding. Collaborative
proposals, including those that advance the program's goals
enumerated in subsection (2), may be given preference.

(b) For fiscal year 2008-2009, grants shall be awarded by
the State Surgeon General, after consultation with the
Biomedical Research <u>Commission</u> Advisory Council, on the basis of
scientific merit <u>through</u>, as determined by an open, competitive
peer review process that ensures objectivity, consistency, and
high quality.

657 (C) Beginning in fiscal year 2009-2010, and each fiscal year thereafter, the State Surgeon General shall submit to the 658 659 Legislature by February 1 a priority list for cancer research 660 funding by the Legislature based on the recommendations of the 661 commission after peer review and scoring of the applications 662 received. Recommendations to the Legislature shall be in the form of a list submitted by the State Surgeon General of the 663 commission's rank order of priority from the proposal with the 664 highest priority through the proposal with the lowest priority, 665 666 including the recommended dollar amount and duration for each

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667 proposal. The State Surgeon General may not reject or modify the commission's recommendations. Successful applicants shall be 668 669 awarded grants by the State Surgeon General based upon the 670 recommendations of the commission and the final funding decision 671 made by the Legislature. 672 Beginning in fiscal year 2009-2010, and each fiscal (d) 673 year thereafter, the commission's overall ranking of grant 674 applications shall be based on the score awarded to the proposal 675 by peer reviewers on the basis of scientific merit through an 676 open competitive peer review process that ensures objectivity, consistency, and high quality and the commission's determination 677 678 of the following: 1. The projected impact that the proposed research will 679 680 have on cancer research at the time the grant is awarded; The likelihood or possibility that the proposed 681 2. research will result in new treatment modalities or technology 682 683 during the term of the grant; and 684 Whether the research proposed offers an efficient use 3. 685 of state funds in order to prevent or cure cancer. 686 The following types of applications shall be (e) 687 considered for funding: 688 Investigator-initiated research grants. 1. 689 2. Institutional research grants. 690 Collaborative research grants, including those that 3. advance the finding of cures through basic or applied research. 691 Beginning in fiscal year 2009-2010, and each fiscal 692 (f) 693 year thereafter, state funds shall only be provided for research

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# 694 that was applied for, reviewed, and recommended in accordance 695 with this section.

(q) (b) In order to ensure that all proposals for research 696 697 funding are appropriate and are evaluated fairly on the basis of 698 scientific merit, the State Surgeon General, in consultation 699 with the commission <del>council</del>, shall appoint a peer review panel 700 of independent, scientifically qualified individuals to review 701 the scientific content of each proposal and establish its 702 priority score. The priority scores shall be forwarded to the commission and its committees council and must be considered in 703 704 determining which proposals shall be recommended for funding.

705 (h) (c) The commission, the committees, council and the 706 peer review panel shall establish and follow rigorous guidelines 707 for ethical conduct and adhere to a strict policy with regard to 708 conflicts of interest. A member of the commission, a committee, 709 council or the panel may not participate in any discussion or 710 decision with respect to a research proposal by any firm, 711 entity, or agency with which the member is associated as a 712 member of the governing body or as an employee or with which the member has entered into a contractual arrangement. Meetings of 713 714 the commission, the committees, council and the peer review 715 panels are subject to chapter 119, s. 286.011, and s. 24, Art. I 716 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.

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722 Beginning in fiscal year 2006-2007, the sum of \$9 (5) 723 million is appropriated annually from recurring funds in the 724 General Revenue Fund to the Biomedical Research Trust Fund within the Department of Health for purposes of the William G. 725 726 "Bill" Bankhead, Jr., and David Coley Cancer Research Program 727 and shall be distributed pursuant to this section to provide 728 grants to researchers seeking cures for cancer, with emphasis given to the goals enumerated in s. 381.921. From the total 729 730 funds appropriated, an amount of up to 10 percent may be used for administrative expenses. 731

732 (6) By June 1, 2009, the Division of Statutory Revision of
733 the Office of Legislative Services shall certify to the
734 President of the Senate and the Speaker of the House of
735 Representatives the language and statutory citation of this
736 section, which is scheduled to expire January 1, 2011.

737 (7) The Legislature shall review the performance, the
738 outcomes, and the financial management of the William G. "Bill"
739 Bankhead, Jr., and David Coley Cancer Research Program during
740 the 2010 Regular Session of the Legislature and shall determine
741 the most appropriate funding source and means of funding the
742 program based on its review.

743 (6) (8) This section expires June 30 January 1, 2011,
744 unless reviewed and reenacted by the Legislature before that
745 date.

746Section 9. Subsection (1) and paragraph (a) of subsection747(2) of section 458.324, Florida Statutes, are amended to read:748458.324748Breast cancer; information on treatment

749 alternatives.--

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750	(1) DEFINITIONAs used in this section, the term
751	"medically viable," as applied to treatment alternatives, means
752	modes of treatment generally considered by the medical
753	profession to be within the scope of current, acceptable
754	standards, including treatment alternatives described in the
755	written summary prepared by the Florida Cancer Control and
756	Research Advisory Council in accordance with s. 1004.435(4)(m).
757	(2) COMMUNICATION OF TREATMENT ALTERNATIVESEach
758	physician treating a patient who is, or in the judgment of the
759	physician is at high risk of being, diagnosed as having breast
760	cancer shall inform such patient of the medically viable
761	treatment alternatives available to such patient; shall describe
762	such treatment alternatives; and shall explain the relative
763	advantages, disadvantages, and risks associated with the
764	treatment alternatives to the extent deemed necessary to allow
765	the patient to make a prudent decision regarding such treatment
766	options. In compliance with this subsection:
767	(a) The physician may, in his or her discretion:
768	1. Orally communicate such information directly to the
769	patient or the patient's legal representative;
770	2. Provide the patient or the patient's legal
771	representative with a copy of <u>a</u> <del>the</del> written summary <del>prepared in</del>
772	accordance with s. 1004.435(4)(m) and express a willingness to
773	discuss the summary with the patient or the patient's legal
774	representative; or
775	3. Both communicate such information directly and provide

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a copy of the written summary to the patient or the patient's

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CS/HB 7061, Engrossed 1 777 legal representative for further consideration and possible later discussion. 778 779 780 Nothing in this subsection shall reduce other provisions of law 781 regarding informed consent. 782 Section 10. Subsection (1) and paragraph (a) of subsection 783 (2) of section 459.0125, Florida Statutes, are amended to read: 784 459.0125 Breast cancer; information on treatment 785 alternatives.--(1) DEFINITION.--As used in this section, the term 786 787 "medically viable," as applied to treatment alternatives, means 788 modes of treatment generally considered by the medical 789 profession to be within the scope of current, acceptable 790 standards, including treatment alternatives described in the 791 written summary prepared by the Florida Cancer Control and 792 Research Advisory Council in accordance with s. 1004.435(4)(m). 793 (2)COMMUNICATION OF TREATMENT ALTERNATIVES.--It is the 794 obligation of every physician treating a patient who is, or in 795 the judgment of the physician is at high risk of being, 796 diagnosed as having breast cancer to inform such patient of the 797 medically viable treatment alternatives available to such 798 patient; to describe such treatment alternatives; and to explain 799 the relative advantages, disadvantages, and risks associated with the treatment alternatives to the extent deemed necessary 800 to allow the patient to make a prudent decision regarding such 801

802 803

The physician may, in her or his discretion: (a)

treatment options. In compliance with this subsection:

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Orally communicate such information directly to the
 patient or the patient's legal representative;

2. Provide the patient or the patient's legal representative with a copy of <u>a</u> the written summary <del>prepared in</del> accordance with s. 1004.435(4)(m) and express her or his willingness to discuss the summary with the patient or the patient's legal representative; or

3. Both communicate such information directly and provide
a copy of the written summary to the patient or the patient's
legal representative for further consideration and possible
later discussion.

815

816 Nothing in this subsection shall reduce other provisions of law817 regarding informed consent.

818 Section 11. Subsections (7), (8), and (12) of section 819 1004.445, Florida Statutes, as amended by chapter 2007-332, Laws 820 of Florida, are amended to read:

821 1004.445 Johnnie B. Byrd, Sr., Alzheimer's Center and
822 Research Institute.--

823 The board of directors of the not-for-profit (7)824 corporation shall create a council of scientific advisers to the 825 chief executive officer comprised of leading researchers, 826 physicians, and scientists. The council shall review programs 827 and recommend research priorities and initiatives to maximize the state's investment in the institute. The members of the 828 council shall be appointed by the board of directors of the not-829 for-profit corporation. Each member of the council shall be 830

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appointed to serve a 2-year term and may be reappointed to thecouncil. This subsection expires on June 30, 2009.

Applications for Alzheimer's disease research 833 (8)(a) 834 funding may be submitted from any university or established 835 research institute in the state. All qualified investigators in 836 the state, regardless of institutional affiliation, shall have 837 equal access and opportunity to compete for the research funding. Grants shall be awarded by the board of directors of 838 839 the not-for-profit corporation on the basis of scientific merit, 840 as determined by an open, competitive peer review process that 841 ensures objectivity, consistency, and high quality. The following types of applications shall be considered for funding: 842

843

1. Investigator-initiated research grants.

844

2. Institutional research grants.

3. Collaborative research grants, including those thatadvance the finding of cures through basic or applied research.

(b) Preference may be given to grant proposals that foster
collaboration among institutions, researchers, and community
practitioners because these proposals support the advancement of
cures through basic or applied research, including clinical
trials involving Alzheimer's patients and related networks.

(c) To ensure that all proposals for research funding are 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

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859 priority scores shall be forwarded to the council and must be 860 considered by the board of directors of the not-for-profit 861 corporation in determining which proposals shall be recommended 862 for funding.

863 (d) The council of scientific advisors and the peer review 864 panel shall establish and follow rigorous guidelines for ethical 865 conduct and adhere to a strict policy with regard to conflict of interest. All employees, members of the board of directors, and 866 867 affiliates of the not-for-profit corporation shall follow the same rigorous quidelines for ethical conduct and shall adhere to 868 the same strict policy with regard to conflict of interest. A 869 870 member of the council or panel may not participate in any discussion or decision with respect to a research proposal by 871 872 any firm, entity, or agency with which the member is associated 873 as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement. 874 875 Meetings of the council and the peer review panels are subject 876 to chapter 119, s. 286.011, and s. 24, Art. I of the State 877 Constitution.

878

(e) This subsection expires on June 30, 2009.

879 (12) (a) Beginning in fiscal year 2008-2009 2007-2008, the 880 sum of \$3.75 <del>\$13.5</del> million is appropriated annually from 881 recurring funds in the General Revenue Fund to the Grants and Donations Trust Fund within the Department of Elderly Affairs 882 for the Johnnie B. Byrd, Sr., Alzheimer's Center and Research 883 Institute at the University of South Florida for the purposes as 884 provided under paragraph (6)(a), conducting and supporting 885 research, providing institutional research grants and 886

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investigator-initiated research grants, developing and operating integrated data projects, and providing assistance to statutorily designated memory disorder clinics as provided under s. 430.502. Not less than 80 percent of the appropriated funds shall be expended for these purposes, and not less than 20 percent of the appropriated funds shall be expended for peerreviewed investigator-initiated research grants.

(b) Beginning in fiscal year 2009-2010, and each fiscal 894 895 year thereafter, the sum appropriated in paragraph (a) shall be 896 used for programs that fulfill the mission of the institute in education, treatment, prevention, and early detection of 897 898 Alzheimer's disease, developing and operating integrated data 899 projects, and providing assistance to statutorily designated 900 memory disorder clinics. If the institute intends to conduct research using state funds, it shall compete for funding through 901 902 the James and Esther King Biomedical Research Program pursuant 903 to s. 215.5602.

904 Section 12. Sections 381.0404, 381.85, 381.912, 381.92, 905 <u>381.921, 381.98, 381.981, and 1004.435, Florida Statutes, are</u> 906 repealed.

907 Section 13. <u>If any provision of this act or the</u>

908 application thereof to any person or circumstance is held

909 invalid, the invalidity does not affect other provisions or

910 applications of the act which can be given effect without the

911 invalid provision or application, and to this end the provisions

- 912 of this act are declared severable.
- 913

Section 14. This act shall take effect July 1, 2008.

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