A bill to be entitled 1 2 An act relating to biomedical research; 3 creating s. 240.5125, F.S.; establishing a 4 biomedical research program within the 5 Department of Health; providing goals; providing for use of funds appropriated from 6 7 the Tobacco Settlement Trust Fund; creating the 8 Biomedical Research Advisory Council; providing 9 for membership and organization; providing for staff and assistance of the department; 10 11 providing duties of the council; providing for 12 applications for and award of biomedical 13 research grants and fellowships; providing for 14 appointment of peer review panels; providing 15 for ethical conduct of the council and peer 16 review panels; authorizing the department to contract for administration of the program; 17 providing a limitation of administrative 18 expenses; authorizing the department to adopt 19 20 rules; requiring an annual report; providing an 21 appropriation; providing an effective date. 22 23 Be It Enacted by the Legislature of the State of Florida: 24 25 Section 1. Section 240.5125, Florida Statutes, is 26 created to read: 27 240.5125 Biomedical research.--28 There is established within the Department of 29 Health a biomedical research program to support research 30 initiatives that address the health care problems of

Floridians in the areas of cancer, cardiovascular disease,

 stroke, and pulmonary disease. The long-term goals of the
program shall be to:

- (a) Improve the health of Florida's citizens by researching better treatments for cancer, cardiovascular disease, stroke, and pulmonary disease.
- (b) Expand the foundation of biomedical knowledge relating to the diagnosis and treatment of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.
- (c) Improve the quality of Florida's academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers.
- (d) Increase the state's per capita funding for biomedical research by undertaking new initiatives in biomedical research that will attract additional funding from outside the state.
- (e) Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.
- (2) Funds appropriated from the Tobacco Settlement
 Trust Fund to the Department of Health for the purposes of
 this section shall be used exclusively for the award of grants
 and fellowships, under the program established in this
 section, for research relating to the diagnosis and treatment
 of diseases related to tobacco use, including cancer,
 cardiovascular disease, stroke, and pulmonary disease, and for
 expenses incurred in the administration of this section.
- (3) There is created within the Department of Health the Biomedical Research Advisory Council.

1	(a) The council shall consist of nine members,
2	including: the chief executive officer of the Florida Division
3	of the American Cancer Society, or a designee; the chief
4	executive officer of the Florida/Puerto Rico Affiliate of the
5	American Heart Association, or a designee; and the chief
6	executive officer of the American Lung Association of Florida,
7	or a designee. The Governor shall appoint the remaining six
8	members of the council, as follows:
9	1. Two members with expertise in the field of
10	biomedical research.
11	2. One member with expertise in the field of
12	behavioral or social research.
13	3. One member from a professional medical
14	organization.
15	4. One member from a research university in the state.
16	5. One member representing the general population of
17	the state.
18	
19	In making his appointments, the Governor shall select
20	primarily, but not exclusively, Floridians with biomedical and
21	lay expertise in the general areas of cancer, cardiovascular
22	disease, stroke, and pulmonary disease. The Governor's
23	appointments shall be for a 3-year term and shall reflect the
24	diversity of the state's population. A council member
25	appointed by the Governor may not serve more than two
26	consecutive terms.
27	(b) The council shall adopt internal organizational
28	procedures as necessary for its efficient organization.
29	(c) The department shall provide such staff,

information, and other assistance as is reasonably necessary
 to assist the council in carrying out its responsibilities.

1	(d) Members of the council shall serve without
2	compensation, but may receive reimbursement as provided in s.
3	112.061 for travel and other necessary expenses incurred in
4	the performance of their official duties.
5	(4) The council shall advise the Secretary of Health
6	as to the direction and scope of the biomedical research
7	program. The responsibilities of the council may include, but
8	are not limited to:
9	(a) Providing advice on program priorities and
10	emphases.
11	(b) Providing advice on the overall program budget.
12	(c) Participating in periodic program evaluation.
13	(d) Assisting in the development of guidelines to
14	ensure fairness, neutrality, and adherence to the principles
15	of merit and quality in the conduct of the program.
16	(e) Assisting in the development of appropriate
17	linkages to nonacademic entities, such as voluntary
18	organizations, health care delivery institutions, industry,
19	government agencies, and public officials.
20	(f) Developing criteria and standards for the award of
21	research grants.
22	(g) Developing administrative procedures relating to
23	solicitation, review, and award of research grants and
24	fellowships, to ensure an impartial, high-quality peer review
25	system.
26	(h) Developing and supervising research peer review
27	panels.
28	(i) Reviewing reports of peer review panels and making
29	recommendations for research grants and fellowships.

(j) Developing and providing oversight regarding

30

31 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) Grants and fellowships shall be awarded by the Secretary of Health, after consultation with the council, on the basis of scientific merit, as determined by an open competitive peer review process that ensures objectivity, consistency, and high quality. The following types of applications shall be 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 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 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.
- establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflict of interest. No member of the council or panel shall 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 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.

- (8) The department may contract on a competitive bid basis with an appropriate entity to administer the program.

 Administrative expenses shall not exceed 15 percent of the total funds available to the program in any given year.
- (9) The department, after consultation with the council, is authorized to adopt rules as necessary to implement the provisions of this section.
- (10) The council shall submit an annual progress report on the state of biomedical research in Florida to the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by February 1. The report shall 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 total amount of biomedical research funding currently 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.
- 29 <u>(f) Progress in the treatment of diseases related to</u>
 30 <u>tobacco use, including cancer, cardiovascular disease, stroke,</u>
 31 and pulmonary disease.

Section 2. There is hereby appropriated from the Tobacco Settlement Trust Fund to the Department of Health for fiscal year 1999-2000 the sum of \$150 million to fund the biomedical research program as provided for in s. 240.5125, Florida Statutes.

Section 3. This act shall take effect July 1, 1999.

HOUSE SUMMARY

Establishes a biomedical research program under the Department of Health to support research in diseases related to tobacco use, including cancer, cardiovascular diseases, stroke, and pulmonary diseases. Provides for funding from the Tobacco Settlement Trust Fund. Creates a Biomedical Research Advisory Council to advise and assist the Secretary of Health in developing and administering the program and awarding research grants and fellowships the Secretary of Health in developing and administering the program and awarding research grants and fellowships. Provides for creation of peer review panels to provide independent, scientific review of research proposals. Provides for appointment and duties of council and panel members. Provides procedures for application for and award of grants and fellowships. Provides for ethical conduct of the council and panels. Provides responsibilities of the Department of Health. Authorizes the department to contract by competitive bid for administration of the program. Authorizes the department to adopt rules. Requires the council to provide an annual progress report to the Governor, Secretary of Health, and Legislature. Provides an appropriation.