

FIRST REGULAR SESSION

[PERFECTED]

HOUSE COMMITTEE SUBSTITUTE FOR

HOUSE BILL NO. 688

92ND GENERAL ASSEMBLY

Reported from the Committee on Health Care Policy April 14, 2003, with recommendation that the House Committee Substitute for House Bill No. 688 Do Pass.

Taken up for Perfection April 22, 2003. House Committee Substitute for House Bill No. 688 ordered Perfected and printed, as amended.

STEPHEN S. DAVIS, Chief Clerk

2074L.02P

AN ACT

To amend chapter 196, RSMo, by adding thereto eleven new sections relating to the life sciences research trust fund.

Be it enacted by the General Assembly of the state of Missouri, as follows:

Section A. Chapter 196, RSMo, is amended by adding thereto eleven new sections, to
2 be known as sections 196.1100, 196.1103, 196.1106, 196.1109, 196.1112, 196.1115, 196.1118,
3 196.1121, 196.1124, 196.1127, and 196.1130, to read as follows:

196.1100. 1. There is hereby established in the state treasury the "Life Sciences
2 Research Trust Fund" to be held separate and apart from all other public moneys and
3 funds of the state, including but not limited to the tobacco securitization settlement trust
4 fund established in section 8.550, RSMo. The state treasurer shall deposit into the fund
5 twenty-five percent of all moneys received from the master settlement agreement, as
6 defined in section 196.1000, beginning in fiscal year 2007 and in perpetuity thereafter.
7 Moneys in the fund shall not be subject to appropriation for purposes other than those
8 provided in sections 196.1100 to 196.1130 without a majority vote in each house of the
9 general assembly. All moneys in the fund shall be used for the purposes of sections
10 196.1100 to 196.1130 only. Notwithstanding the provisions of section 33.080, RSMo, to the
11 contrary, the moneys in the fund shall not revert to the credit of general revenue at the end
12 of the biennium.

13 2. Moneys in the life sciences research trust fund shall be used strategically, in
14 cooperation with other governmental and not-for-profit private entities to enhance the

15 capacity of the state of Missouri's ability to perform research to better serve the health and
16 welfare of the residents of the state of Missouri as a center of life sciences research and
17 development by building on the success of research institutions located in Missouri,
18 creating in and attracting to Missouri new research and development institutions,
19 commercializing the life sciences technologies developed by such institutions, and
20 enhancing their capacity to carry out their respective missions.

196.1103. The management, governance, and control of moneys appropriated from
2 the life sciences research trust fund shall be vested in the "Life Sciences Research Board"
3 which is hereby created in the office of administration as a type III division and which shall
4 consist of seven members. The following provisions shall apply to the life sciences research
5 board and its members:

6 (1) Each member shall be appointed by the governor with the advice and consent
7 of the senate pursuant to the procedures herein set forth for a term of four years; except
8 that, of the initial members of the board appointed, three shall be appointed for two-year
9 terms and four shall be appointed to four-year terms;

10 (2) The members of the board shall be generally familiar with the life sciences and
11 current research trends and developments with either technical or scientific expertise in
12 life sciences and with an understanding of the application of the results of life sciences
13 research. The appointment of a person to the life sciences research committee created by
14 Executive Order 01-10 issued by the governor on July 23, 2002, shall not disqualify a
15 person from serving as a member, either contemporaneously or later, on the life sciences
16 research board;

17 (3) No member of the life sciences research board shall serve more than two
18 consecutive full four-year terms;

19 (4) The members of the life sciences research board shall receive no salary or other
20 compensation for their services as a member of the board, but shall receive reimbursement
21 for their actual and necessary expenses incurred in performance of their duties as members
22 of the board.

196.1106. Centers for life sciences research shall be established and shall be subject
2 to the following provisions:

3 (1) A "center for excellence for life sciences research" means a system or regional
4 consortium of public and private not-for-profit academic, research, or health care
5 institutions or organizations engaged in competitive research in targeted fields consistent
6 with the strategic purposes of life sciences research as provided in sections 196.1100 to
7 196.1130;

8 (2) The life sciences research board shall monitor and adopt such rules as are

9 necessary to assure quality and accountability in the operation of the centers for excellence
10 for life sciences research;

11 (3) One St. Louis area center for excellence may be established within the
12 geographical area encompassing the City of St. Louis and St. Louis, St. Charles, Jefferson,
13 and Franklin counties. If any part of a municipality is located within any one such county
14 and also encompasses a part of another county in this state, the entire area encompassed
15 within the city limits of such municipality shall be a part of the geographical area of the St.
16 Louis area center for excellence;

17 (4) One Kansas City area center for excellence may be established within the
18 geographical area encompassing Jackson, Clay, Andrew, Buchanan, and Platte counties.
19 If any part of a municipality is located within any one such county and also encompasses
20 a part of another county in this state, the entire area encompassed within the city limits of
21 such municipality shall be a part of the geographical area of the Kansas City area center
22 for excellence;

23 (5) One Springfield center for excellence may be established within the
24 geographical area encompassing Greene, Christian, and Webster counties;

25 (6) A Missouri statewide center for excellence may be established that shall
26 encompass the institutions and campuses within the University of Missouri system and
27 those regions of Missouri not encompassed within another center for excellence; provided
28 that the University of Missouri-Kansas City and the University of Missouri-St. Louis shall
29 participate in the centers for excellence in their respective geographical regions;

30 (7) The life sciences research board shall receive and review suggestions for the
31 formation and composition of the initial centers for excellence. After receiving and
32 reviewing such suggestions, the life sciences research board shall determine the initial
33 composition, and shall consider and approve the organizational plan and structure of the
34 St. Louis area, Kansas City area, and Missouri statewide centers for excellence;

35 (8) Before any center for excellence is considered to be a center for excellence for
36 life sciences research under sections 196.1100 to 196.1130, its composition and
37 organizational structure shall be approved by the life sciences research board;

38 (9) Any center for excellence for life sciences research that is established within a
39 geographical area specified in sections 196.1100 to 196.1130 shall be comprised of a
40 consortium of public and private not-for-profit academic, research, or health care
41 institutions or organizations that have collectively at least fifteen million dollars in annual
42 research expenditures in the life sciences, including a collective minimum of two million
43 dollars in basic research in life sciences;

44 (10) Each center for excellence for life sciences research shall appoint a screening

45 **committee. The centers, through their screening committees, shall solicit, collect, prioritize,**
46 **and forward to the life sciences research board proposed research initiatives for**
47 **consideration for funding by the board. Members of each screening committee shall**
48 **generally be familiar with the life sciences and current trends and developments with either**
49 **technical or scientific expertise in the life sciences with an understanding of life sciences**
50 **and with an understanding of the application of the results of life sciences research. No**
51 **member of a screening committee shall be employed by any public or private entity eligible**
52 **to receive financial support from the life sciences research trust fund; and**

53 **(11) The centers for excellence for life sciences research shall have any and all**
54 **powers attendant to carrying out the operations that are not contrary to the provisions of**
55 **sections 196.1100 to 196.1130 or any rules, guidelines, or decisions adopted by the life**
56 **sciences research board.**

196.1109. All moneys that are appropriated by the general assembly from the life
2 **sciences research trust fund shall be appropriated to the life sciences research board to**
3 **increase the capacity for quality of life sciences research in the state of Missouri and to**
4 **thereby:**

5 **(1) Improve the quantity and quality of life sciences research, including but not**
6 **limited to basic research (including the discovery of new knowledge), translational research**
7 **(including translating knowledge into a usable form), developmental research, and clinical**
8 **research (including the literal application of a therapy or intervention to determine its**
9 **efficacy), including but not limited to health research in human development and aging,**
10 **cancer, endocrine, cardiovascular, neurological, pulmonary, and infectious disease, and**
11 **plant sciences, including but not limited to nutrition and food safety; and**

12 **(2) Enhance technology transfer and technology commercialization derived from**
13 **institutions or organizations within the centers for excellence. For purposes of sections**
14 **196.1100 to 196.1130, "technology transfer and technology commercialization" includes**
15 **stages of the regular business cycle occurring after research and development of a life**
16 **science technology, including but not limited to reduction to practice, proof of concept, and**
17 **achieving federal Food and Drug Administration, United States Department of**
18 **Agriculture, or other regulatory requirements in addition to the definition in section**
19 **348.251, RSMo.**

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21 **Funds received by the board may be used for purposes authorized in sections 196.1100 to**
22 **196.1130 and shall be subject to the restrictions of sections 196.1100 to 196.1130, including**
23 **but not limited to the costs of personnel, supplies, equipment, and renovation or**
24 **construction of physical facilities; provided that in any single fiscal year no more than ten**

25 percent of the moneys appropriated shall be used for the construction of physical facilities
26 and further provided that in any fiscal year eighty percent of the moneys shall be
27 appropriated to build research capacity and twenty percent of the moneys shall be
28 appropriated to promote life science technology transfer and technology
29 commercialization. Twenty percent of the moneys shall be appropriated to promote the
30 development of research of tobacco-related illnesses.

196.1112. In determining projects to authorize, the life sciences research board
2 shall consider those proposals endorsed by a center for excellence, subject to a process of
3 peer review conducted under the auspices of the board, and shall also consider the
4 potential of any proposal to bring both health and economic benefits to the people of
5 Missouri. Specifically, at least eighty percent of the moneys that are appropriated to the
6 board in each fiscal year shall be distributed to the institutions or organizations whose
7 programs and proposals have been recommended by a center for excellence that meets the
8 requirements set forth in subdivisions (8) and (9) of section 196.1106. Collectively, the
9 institutions or organizations within a single center for excellence shall receive in a single
10 fiscal year no more than fifty percent of the moneys appropriated to the board during such
11 fiscal year. No single institution or organization shall receive in any consecutive three-
12 fiscal-year period more than forty percent of the moneys appropriated to the board during
13 such three-fiscal-year period.

196.1115. 1. The moneys appropriated to the life sciences research board that are
2 not distributed by the board in any fiscal year to a center for excellence or a center for
3 excellence endorsed program pursuant to section 196.1112, if any, shall be held in reserve
4 by the board or shall be awarded on the basis of peer review panel recommendations for
5 capacity building initiatives proposed by public and private not-for-profit academic,
6 research, or health care institutions or organizations, or individuals engaged in competitive
7 research in targeted fields consistent with the provisions of sections 196.1100 to 196.1130.

2. The life sciences research board may, in view of the limitations expressed in
9 section 196.1130:

10 (1) Award and enter into grants or contracts relating to increasing Missouri's
11 research capacity;

12 (2) Make provision for peer review panels to recommend and review research
13 projects;

14 (3) Contract for administrative and support services;

15 (4) Lease or acquire facilities and equipment;

16 (5) Employ administrative staff; and

17 (6) Receive, retain, hold, invest, disburse or administer any moneys that it receives

18 from appropriations or from any other source.

19 **3. The life sciences research board shall utilize as much of the moneys as reasonably**
20 **possible for building capacity to do research rather than for administrative expenses. The**
21 **board shall not in any fiscal year expend more than two percent of the total moneys**
22 **appropriated to it and of the moneys that it has in reserve or has received from other**
23 **sources for its own administrative expenses; provided, however, that the general assembly**
24 **by appropriation from the life sciences research trust fund may authorize a limited amount**
25 **of additional moneys to be expended for administrative costs.**

196.1118. The life sciences research board shall make provision for and secure the
2 **state auditor or outside public accounting firm an annual audit of its financial affairs and**
3 **the moneys expended from the life sciences research trust fund. Such audit shall be**
4 **performed on a fiscal year basis and the cost of such audit shall not be considered as an**
5 **administrative expense for purposes of subsection 3 of section 196.1115. The board shall**
6 **make copies of each audit available to the public. Every three years the board, with the**
7 **assistance of its staff or independent contractors as determined by the board, shall prepare**
8 **a comprehensive report assessing the work and progress of the life sciences research**
9 **program. Such assessment report shall analyze the impact of the board's programs,**
10 **grants, and contracts performed, shall be provided to the governor and the general**
11 **assembly, and shall be available to the public. The cost of such assessment report shall not**
12 **be considered an administrative expense for purposes of subsection 3 of section 196.1115.**

196.1121. 1. Grant or contract awards made with moneys appropriated from the
2 **life sciences research trust fund shall provide for the reimbursement of costs. Whether**
3 **reimbursement of specific costs is allowed depends on the application of a four-part test**
4 **balancing which shall include:**

- 5 **(1) The reasonableness of the cost;**
- 6 **(2) The connection to the grant or contract;**
- 7 **(3) The consistency demonstrated in assigning costs to the grant or contract; and**
- 8 **(4) Conformance with the specific terms and conditions of the award or contract.**

9

10 **The life sciences research board may from time to time issue rules and guidelines consistent**
11 **with such four-part test and provide grant and contract recipients with a list or other**
12 **explanation of regularly permitted costs.**

13 **2. Grant and contract recipients shall preserve research freedom, ensure timely**
14 **disclosure of their research findings to the scientific community, including through**
15 **publications and presentations at scientific meetings, and promote utilization,**
16 **commercialization, and public availability of their inventions and other intellectual**

17 **property developed as a general institutional policy. Institutions or organizations receiving**
18 **grant or contract awards shall retain all right, title, and interest, including all intellectual**
19 **property rights, in and to any and all inventions, ideas, data, improvements, modifications,**
20 **know-how, creations, copyrightable material, trade secrets, methods, processes,**
21 **discoveries, and derivatives, regardless of patentability, that are made in the performance**
22 **of work under a grant award. The life sciences research board shall adopt reasonable**
23 **rules to ensure that any such intellectual property rights are utilized reasonably and in a**
24 **manner that is in the public interest.**

196.1124. No member of the life sciences research board shall be employed by any
2 **public or private entity entitled to receive financial support from the life sciences research**
3 **trust fund, or participate in the making of any decision by the board to make any grant to**
4 **the board member, any person who is related to the board member within the fourth**
5 **degree of consanguinity or affinity, any public entity for which the board member serves**
6 **as an officer, director, or other member of the entity's governing body, or any private**
7 **entity for which the board member or the member's spouse is employed, serves as an**
8 **officer, director, or other member of the entity's governing body. The board may from**
9 **time to time issue conflict of interest guidelines and requirements with respect to the**
10 **administration of the life sciences research program, to govern the actions of its employees**
11 **and agents, and to implement the provisions of section 196.1124.**

196.1127. 1. The moneys appropriated to the life sciences research board pursuant
2 **to sections 196.1100 to 196.1124 shall be subject to the provisions of this section.**

3 **2. As used in this section, the following terms shall mean:**

4 **(1) "Abortion services", include performing, inducing, or assisting with abortions,**
5 **as defined in section 188.015, RSMo, or encouraging patients to have abortions, referring**
6 **patients for abortions not necessary to save the life of the mother, or development of drugs,**
7 **chemicals, or devices intended to be used to induce an abortion;**

8 **(2) "Child", a human being recognized as a minor pursuant to the laws of this state,**
9 **including if in vivo, an unborn child as defined in section 188.015, RSMo, and if in vitro,**
10 **a human being at any of the stages of biological development of an unborn child from**
11 **conception or inception onward;**

12 **(3) "Conception", the same meaning as such term is defined in section 188.015,**
13 **RSMo;**

14 **(4) "Facilities and administrative costs", those costs that are incurred for common**
15 **or joint objectives and therefore cannot be identified readily and specifically with a**
16 **particular research project or any other institutional activity;**

17 **(5) "Human cloning", the creation of a human being by any means other than by**

18 the fertilization of an oocyte of a human female by a sperm of a human male;

19 (6) "Prohibited human research", research in a research project in which there is
20 the taking or utilization of the organs, tissues, or cellular material of:

21 (a) A deceased child, unless consent is given by the parents in a manner provided
22 in sections 194.210 to 194.290, RSMo, relating to anatomical gifts, and neither parent
23 caused the death of such child or consented to another person causing the death of such
24 child;

25 (b) A living child, when the intended or likely result of such taking or utilization
26 is to kill or cause harm to the health, safety, or welfare of such child, or when the purpose
27 is to target such child for possible destruction in the future;

28 (7) "Public funds", include:

29 (a) Any moneys received or controlled by the state of Missouri or any official,
30 department, division, agency, or political subdivision thereof, including but not limited to
31 moneys derived from federal, state, or local taxes, gifts, or grants from any source,
32 settlements of any claims or causes of action, public or private, bond proceeds, federal
33 grants or payments, or intergovernmental transfers;

34 (b) Any moneys received or controlled by an official, department, division, or
35 agency of state government or any political subdivision thereof, or to any person or entity
36 pursuant to appropriation by the general assembly or governing body of any political
37 subdivision of this state;

38 (8) "Research project", research proposed to be funded by an award of public
39 funds conducted under the auspices of the entity or entities that applied for and received
40 such award, regardless of whether the research is funded in whole or in part by such
41 award. Such research shall include basic research, including the discovery of new
42 knowledge; translational research, including translational knowledge in a usable form; and
43 developmental research and clinical research, including but not limited to health research
44 in human development and aging, cancer, endocrine, cardiovascular, neurological,
45 pulmonary, and infectious disease.

46 3. Public funds shall not be expended, paid, or granted to or on behalf of an existing
47 or proposed research project that involves abortion services, human cloning, or prohibited
48 human research. A research project that receives an award of public funds shall not share
49 costs with another research project, person, or entity not eligible to receive public funds
50 pursuant to this subsection; provided that a research project that receives an award of
51 public funds may pay a pro rata share of facilities and administrative costs determined in
52 the award of public funds according to standards that ensure that public funds do not in
53 any way subsidize facilities and administrative costs of other research projects, persons,

54 or entities not eligible to receive public funds pursuant to this subsection. The application
55 for an award of public funds shall set forth the proposed rates of pro rata cost
56 reimbursement and shall provide supporting data and rationale for such rates. All
57 applicants for and recipients of awards of public funds shall comply with the cost
58 accounting principles set forth in Part 9905 of Title 48 of the Code of Federal Regulations,
59 or successor regulations, in connection with the application for and administration of the
60 research project. All moneys derived from an award of public funds shall be expended
61 only by checks, drafts, or electronic transfers using a separate accounting process
62 maintained for each research project. No moneys derived from an award of public funds
63 shall be used to cover costs for any other research project or to any other person or entity.
64 No moneys derived from an award of public funds shall be passed through to any other
65 research project, person, or entity unless included in the original application for the award
66 of public funds or in subsequent amendments or requests to use separate contractors. A
67 research project that receives an award of public funds shall maintain financial records
68 that demonstrate strict compliance with this subsection. Any audit conducted pursuant
69 to any grant or contract awarding public funds shall also certify whether there is
70 compliance with this subsection and shall note any noncompliance as a material audit
71 finding.

72 4. The provisions of this section shall inure to the benefit of all residents of this
73 state. Any taxpayer of this state or any political subdivision of this state shall have
74 standing to bring suit against the state of Missouri or any official, department, division,
75 agency, or political subdivision of this state, and any recipient of public funds who or
76 which is in violation of this subsection in any circuit court with jurisdiction to enforce the
77 provisions of this section.

78 5. This section shall not be construed to permit or make lawful any conduct that
79 is otherwise unlawful pursuant to the laws of this state.

80 6. Any provision of this section is not severable from any appropriation subject to
81 this section or any application declared by any court to be subject to this section. If any
82 provision of this section is found to be invalid or unconstitutional, any appropriation
83 subject to this section or any appropriation declared by any court to be subject to this
84 section shall be void, invalid, and unenforceable.

196.1130. No rule or portion of a rule promulgated pursuant to the authority of
2 sections 196.1100 to 196.1130 shall become effective unless it has been promulgated
3 pursuant to chapter 536, RSMo.