

FIRST REGULAR SESSION
HOUSE COMMITTEE SUBSTITUTE FOR
SENATE SUBSTITUTE FOR
SENATE COMMITTEE SUBSTITUTE FOR
SENATE BILL NO. 226
91ST GENERAL ASSEMBLY

Reported from the Committee on Miscellaneous Bills & Resolutions, May 10, 2001, with recommendation that the House Committee Substitute for Senate Substitute for Senate Committee Substitute for Senate Bill No. 226 Do Pass.

TED WEDEL, Chief Clerk

0834L.12C

AN ACT

To amend chapter 192, RSMo, by adding thereto eight new sections relating to a life sciences research program.

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

Section A. Chapter 192, RSMo, is amended by adding thereto eight new sections, to be known as sections 192.1010, 192.1012, 192.1013, 192.1014, 192.1015, 192.1020, 192.1025 and 192.1035, to read as follows:

192.1010. 1. There is hereby established within the department of health, the "Life Sciences Research Program". The program shall be administered by the director of the department of health based upon the recommendations of the "Life Sciences Research Board", which is hereby created. The program shall consist of grant awards designed to achieve the goals stated in subsection 3 of this section.

2. The life sciences research board shall consist of seven members who shall be appointed in the following manner:

(1) Each member shall be appointed by the governor with the advice and consent of the senate for a term of six years, except for the terms of the initial members. The board shall select its own chairperson from among its members;

(2) The members of the board shall be generally familiar with the life sciences and current research trends and developments, with either technical or scientific expertise in life sciences,

and with an understanding of the application of the results of life sciences research;

(3) The initial members of the life sciences research board shall not be appointed until at least six months after the effective date of this section to permit the life sciences citizens' committee to approve the organization and structure of the initial centers for excellence for life sciences research as hereinafter provided;

(4) One member of the board shall be a resident within the geographical area for a St. Louis area center for excellence, as defined in section 192.1012, and shall be referred to as the St. Louis member; one member shall be a resident within the geographical area for a Kansas City area center for excellence, as defined in section 192.1012, and shall be referred to as the Kansas City area member; and one member shall be a resident of this state and shall be referred to as the university member. The remaining four members shall be residents of this state and shall be referred to as at-large members. No more than one at-large member shall reside in a single United States congressional district when appointed. If an additional center for excellence for life sciences research is established for another geographical area pursuant to section 192.1012, the at-large position on the board that next becomes vacant shall become a position on the board for a member who resides within the geographical area of such additional center for excellence;

(5) The first appointees as the St. Louis member and the Kansas City member of the board shall be appointed to two-year terms; the first appointee as the university member of the board shall be appointed to a four-year term; two of the first two appointees as at-large members of the board shall be appointed to four-year terms; and the remaining two initial at-large members shall be appointed to six-year terms. All subsequent appointees shall be appointed to six-year terms;

(6) The St. Louis area center for excellence for life sciences research may recommend one or more persons to the governor for appointment as the St. Louis member of the board; the Kansas City area for excellence for life sciences research may recommend one or more persons to the governor for appointment as the Kansas City member of the board; the University of Missouri system center for excellence for life sciences research may recommend one or more persons to the governor for appointment as the university member of the board; and any additional center for excellence for life sciences research that is created pursuant to section 192.1012 may recommend one or more persons to the governor for appointment as the member of the board from that center's geographic area. Before making any appointment to fill a vacancy in the office of the St. Louis member, the Kansas City member, the university member or a member for an additional center's geographical area, the governor shall take into consideration any such recommendation made pursuant to this subdivision, but the governor shall not be required to follow such recommendations in making an appointment;

(7) No member of the life sciences research board shall serve more than two consecutive

full six-year terms on the board;

(8) No member of the life sciences research board shall participate in the making of any decision to provide a grant-in-aid to such member, any person who is related to such member within the fourth degree of consanguinity or affinity, any public entity for which such member serves as an officer, director or other member of the entity's governing body, or any private entity for which such member or such member's spouse is employed, serves as an officer, director or other member of the entity's governing body. The board may, from time to time, issue conflict of interest guidelines and requirements with respect to the administration of the life sciences research program, the actions of its employees and agents, and the implementation of the provisions set forth in this subdivision.

3. The life sciences research board shall utilize the moneys in the life sciences research fund created in section 192.1014 to increase the capacity and infrastructure for quality life sciences research in the state of Missouri and to improve the quantity and quality of life sciences research. Such research shall include: basic research, including the discovery of new knowledge; translational research, including translating knowledge into a usable form; and developmental research and clinical research, including but not limited to health research in human development and aging, cancer, endocrine, cardiovascular, neurological, pulmonary and infectious disease, and nutrition and food safety.

4. The board shall accept and approve applications for grants-in-aid for projects which address the goals stated in subsection 3 of this section. The applications shall be designed by the department of health and shall contain information necessary to determine the potential benefits of grants-in-aid to be awarded, as well as other information deemed necessary for the administration of this program.

5. In determining projects to authorize, the board shall consider those proposals endorsed by a center for excellence, subject to a process of peer review, and shall also consider the potential of any proposal to bring both health and economic benefit to the people of Missouri. At least eighty percent of the funds that are appropriated to the board in each fiscal year shall be distributed to the institutions or organizations whose programs and proposals have been recommended by a center for excellence. Collectively, the institutions or organizations with a single center for excellence shall receive in any one fiscal year no more than fifty percent of the funds appropriated to the board for that fiscal year. Collectively, the institutions or organizations within a single center for excellence shall receive in any one fiscal year no less than ten percent of the funds appropriated to the board for that fiscal year. No single institution or organization shall receive in any consecutive fiscal three-year period more than forty percent of the funds appropriated to the board during such three-year period.

6. The life sciences research board shall have the authority to:

(1) Award research grants;
(2) Enter into contracts relating to research;
(3) Adopt research standards;
(4) Promulgate rules governing the administration of research programs, research grants, research contracts and licensing contracts, and the reimbursement of costs, utilization of intellectual property rights and conflict of interest guidelines, consistent with sections 192.1010 to 192.1035;

- (5) Make provision for peer review panels to recommend and review research projects;
(6) Contract for administrative and support services;
(7) Lease or acquire facilities and equipment;
(8) Employ administrative staff; and
(9) Receive, retain, hold, invest, disburse and administer any funds which it receives.

7. The funds appropriated to the board that are not expended by the board in a fiscal year to a center for excellence or for a center for excellence endorsed program pursuant to subsection 5 of this section, if any, hereinafter referred to as "remaining funds", shall be held in reserve by the board or shall be awarded on the basis of peer review panel recommendations to research initiatives proposed by public and private not-for-profit academic, research or health care institutions or organizations, or individuals engaged in competitive research in targeted fields consistent with the provisions of this section. The remaining funds appropriated by the board may be used to increase the capacity of the state of Missouri and public and private not-for-profit institutions or organizations located in this state for quality life sciences research. Research projects receiving funding through or endorsed by a center for excellence for life sciences research shall not be eligible for additional funding from the remaining funds. The remaining funds may be awarded for research projects to such public or private institutions or organizations that are a part of a system or regional consortium constituting a center for excellence if such research projects are not endorsed by such center for excellence.

8. The board shall utilize as much of the funds as reasonably possible for research rather than for administrative expenses. The board shall not in any fiscal year expend more than two percent of the total moneys appropriated to it, the moneys which it has in reserve or the moneys which it has received from other sources for its own administrative expenses; provided that the general assembly, by appropriation from the life sciences research fund, may authorize a limited amount of additional funds to be expended for administrative costs.

9. Any rule or portion of a rule, as that term is defined in section 536.010, RSMo, that is created under the authority delegated in sections 192.1010 to 192.1030 shall become effective only if it complies with and is subject to all of the provisions of chapter 536, RSMo, and, if applicable, section 536.028, RSMo. The rulemaking authority granted in such sections and the

provisions of chapter 536, RSMo, are nonseverable and if any of the powers vested with the general assembly pursuant to chapter 536, RSMo, to review, to delay the effective date or to disapprove and annul a rule are subsequently held unconstitutional, then the grant of rulemaking authority and any rule proposed or adopted after August 28, 2001, shall be invalid and void.

192.1012. Centers for excellence for life sciences research shall be established and shall be subject to the following provisions:

(1) A "center for excellence for life sciences research" means a system or regional consortium of public and private not-for-profit academic, research or health care institutions or organizations engaged in competitive research in targeted fields consistent with the strategic purposes of life sciences research as provided in sections 192.1010 to 192.1035;

(2) The life sciences research board shall monitor and promulgate such rules as are necessary to assure quality and accountability in the operations of the centers for excellence for life sciences research;

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

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

(5) A University of Missouri system center for excellence may be established which shall encompass the institutions and campuses within the University of Missouri system. The board of curators of the University of Missouri may determine which institutions and campuses will participate in the University of Missouri system center for excellence, and the extent and nature of such participation. Institutions and campuses of the University of Missouri system that are within the geographical area of another center for excellence may participate in such center unless prohibited by the board of curators;

(6) The board may establish additional geographical areas within the state within which a center for excellence for life sciences research may be established. Prior to establishing such a geographical area within which a new center may be established, the board shall first find and determine that:

(a) A new center for excellence within such geographical area is needed;

(b) Resources are available for a new center for excellence within such geographical area; and

(c) The establishment of a new center for excellence within such geographical area will not adversely affect any existing center for excellence;

(7) The geographical areas specified herein for a St. Louis area center for excellence and a Kansas City area center for excellence, or a geographical area which is hereinafter established by the board for a center for excellence as herein provided may be expanded by the board to include additional contiguous areas within the state;

(8) Any center for excellence for life sciences research that is established within a geographical area specified in this section or a geographical area established by the board shall be comprised of a consortium of public and private not-for-profit academic, research or health care institutions or organizations which collectively have at least fifteen million dollars in annual research expenditures in the life sciences, including a collective minimum of two million dollars in basic research in life sciences;

(9) Each center for excellence for life sciences research shall appoint a screening committee. The centers, through their screening committees, shall solicit, collect, prioritize and forward to the board proposed research initiatives for consideration for funding by the board. Members of each screening committee shall be generally familiar with the life sciences and current trends and developments, with either technical or scientific expertise in the life sciences, with an understanding of life sciences and with an understanding of the application of the results of life sciences research. No member of a screening committee shall be employed by any public or private entity eligible to receive financial support from the board;

(10) The centers for excellence for life sciences research shall have any and all powers attendant to carrying out the operations which are not contrary to the provisions of this section or any rules, guidelines or decisions adopted by the board.

192.1013. 1. To initially implement the provisions of sections 192.1010 to 192.1035, the governor shall appoint a seven-member "Life Sciences Citizens' Committee" within ninety days of the effective date of sections 192.1010 to 192.1035. The members of the committee shall be generally familiar with the life sciences and current research trends and developments, with either technical or scientific expertise in life sciences and with an understanding of the application of the results of life sciences research.

2. The committee shall:

(1) Receive and review suggestions for the formation and composition, determine the initial composition of, and consider and approve the organizational structure of the centers for excellence for life sciences research within the St. Louis area and the Kansas City area before such centers shall be considered as a center for excellence pursuant to sections 192.1010 to

192.1035;

(2) Review, consider and approve the organization plan and structure of the University of Missouri system center for excellence before such center shall be considered a center for excellence pursuant to sections 192.1010 to 192.1035.

3. After the committee has approved the composition and organizational structure of the three centers for excellence in subsection 2 of this section, the committee shall be immediately disbanded, but in no event shall the committee be disbanded later than one year after its appointment. After the committee's disbandment, the board shall perform the functions of the committee.

4. Before any center for excellence is considered to be a center for excellence for life sciences research pursuant to sections 192.1010 to 192.1035, the center's composition and organizational structure shall be approved by the life sciences citizens' committee if that committee is in existence, and if it is not in existence, such approval shall be obtained from the life sciences research board.

5. The appointment of a person to the life sciences citizens' committee shall not disqualify a person from serving as a member, either contemporaneously or later, on the life sciences research board.

192.1014. 1. There is hereby established in the state treasury the "Life Sciences Research Fund" which shall be used only for life sciences research purposes as provided in sections 192.1010 to 192.1035.

2. Moneys in the life sciences research fund shall be used to strategically enhance, in cooperation with other governmental and not-for-profit private entities, the state's ability to serve the health and welfare of the residents of the state as a center of life sciences research and development by building on the success of research institutions located in the state and enhancing their ability to carry out their respective missions.

3. The management, governance and control of moneys in the life sciences research fund shall be vested with the life sciences research board. All moneys appropriated by the general assembly to the life sciences research fund shall be utilized by the life sciences research board.

4. Moneys in the life sciences research fund received by the board may be used for the purposes authorized in sections 192.1010 to 192.1035, including but not limited to the costs of personnel, supplies, equipment and renovation or construction of physical facilities, provided that in any single fiscal year, no more than ten percent of the funds appropriated shall be used for physical facilities.

5. Notwithstanding the provisions of section 33.080, RSMo, to the contrary, moneys in the fund shall not revert to the credit of general revenue at the end of the biennium.

192.1015. The life sciences research board shall make provision for and secure from the

state auditor or outside certified public accounting firm an annual audit of its financial affairs and the funds expended from the life sciences research fund. Such audit shall be performed on a fiscal year basis. The board will make copies of each audit publicly available. Every three years the board with assistance of its staff or independent contractors as determined by the board shall prepare a comprehensive report assessing the work and progress of the life sciences research program. Such assessment report shall analyze the impact of the board's programs and research performed, shall be provided to the governor and members of the general assembly and shall be publicly available.

192.1020. Grant awards made by the life sciences research board shall provide for the reimbursement of costs. Whether reimbursement of particular costs will be allowed depends on the application of a four-part test balancing, which shall include:

- (1) The reasonableness of the cost;
- (2) The connection to the grant;
- (3) The consistency demonstrated in assigning costs to the grant; and
- (4) Conformance with the particular terms and conditions of the award.

192.1025. Grant recipients have an obligation to preserve research freedom, to ensure timely disclosure of their research findings to the scientific community, including through publications and presentations at scientific meetings, and to promote utilization, commercialization and public availability of their inventions and other intellectual property developed in the performance of research funded by a grant award. Institutions or organizations receiving grant awards shall retain all right, title and interest, including all intellectual property rights in and to any inventions, ideas, data, improvement, modifications, discoveries, know-how, creations, copyrightable material, trade secrets, methods, processes, discoveries and derivatives, whether patentable or not, which are made in the performance of work under a grant award. The life sciences research board may, however, adopt reasonable regulations to ensure that any such intellectual property rights are utilized reasonably and in a manner which is in the public interest.

192.1035. All of the provisions of sections 192.1010 to 192.1035 are severable. If any provisions of sections 192.1010 to 192.1035 are found by a court of competent jurisdiction to be unconstitutional or unconstitutionally enacted, the remaining provisions shall be and remain valid.