

FIRST REGULAR SESSION
[P E R F E C T E D]
SENATE SUBSTITUTE FOR
SENATE COMMITTEE SUBSTITUTE FOR
SENATE BILL NO. 226
91ST GENERAL ASSEMBLY

INTRODUCED BY SENATOR GOODE.

Offered April 17, 2001.

Senate Substitute adopted, April 24, 2001.

Taken up for Perfection April 24, 2001. Bill declared Perfected and Ordered Printed, as amended.

TERRY L. SPIELER, Secretary.

0834S.11P

AN ACT

To amend chapter 192, RSMo, by adding thereto five 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 five new sections, to be known as sections 192.1010, 192.1015, 192.1020, 192.1025 and 192.1030, 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 from moneys appropriated from the "Life Sciences Research Fund", which is hereby created in the state treasury. The grant awards shall be designed to achieve the goals stated in subsection 4 of this section.

2. The life sciences research board shall consist of eight 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) Two initial members of the life sciences research board shall be appointed to two-year terms. Three initial members shall be appointed to a four-year term. The remaining three initial members shall be appointed to six-year terms. All subsequent appointees shall be appointed to six-year terms;

(4) No member of the life sciences research board shall serve more than two consecutive full six-year terms on the board;

(5) The director of the department of health shall be a member of the board;

(6) The director of the office of minority health shall be a non-voting member of the board.

3. The life sciences research board shall solicit, collect and prioritize proposed research initiatives for consideration for funding by the board.

4. The life sciences research board shall take applications for grants-in-aid in order 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 safety development and aging, cancer, endocrine, cardiovascular, neurological including nerve regeneration, pulmonary, diagnostic disease and infectious disease, and nutrition and food safety.

5. The applications shall be designed by the department of health in consultation with the board 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. The grant application shall describe in detail the proposed research project and how the research project shall be conducted in compliance with the requirements of 192.1010 to 192.1030. The department of health shall not approve a grant award unless the department makes specific written findings that such research project shall be conducted in compliance with sections 192.1010 to 192.1030. The grant application and the grant award shall be a public record within the meaning of chapter 610, RSMo. The department of health shall promulgate rules in accordance with chapter 536, RSMo, to implement the provisions of this subsection.

6. The department of health shall provide facilities, equipment, administrative and technical support services and administrative staff.

7. In determining projects to authorize, the life sciences research board shall

consider the potential of any proposal to bring both health and economic benefit to the people of Missouri.

8. 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, 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 technical support services;**
- (7) Lease or acquire facilities and equipment;**
- (8) Employ administrative staff; and**
- (9) Receive, disburse and administer any funds appropriated to it.**

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 192.1035 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.

192.1015. 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 account. The audit shall be performed on a fiscal year basis. Any audit shall be paid for by moneys expended from the life sciences research fund, whether performed by the state auditor or outside certified public accounting firm. 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 and all 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 insure that any such intellectual property rights are utilized reasonably and in a manner which is in the public interest.

192.1030. 1. Notwithstanding the provisions of sections 192.1010 to 192.1025, no grant awards shall be paid, granted, or used, to subsidize in whole or in part:

- (1) Abortion services; or**
- (2) Destructive human research; or**
- (3) Development of drugs or chemicals intended to be used to induce an abortion;**

or

- (4) Human cloning.**

2. For the purposes of this section:

(1) "Abortion services" shall mean performing or inducing, assisting in performing or inducing, or referring a woman for, an abortion, except when necessary to save the life of the mother;

(2) "Child" if in utero, shall mean the same as an unborn child, as defined in section 188.015, RSMo; and if ex utero, shall mean a human being at any of the stages of biological development of an unborn child from conception onward;

(3) "Destructive human research" shall mean research in which there is the taking or utilization of the organs, tissue or cellular material of a:

- (a) Deceased child, unless consent was given the manner provided pursuant to**

sections 194.210 to 194.290, RSMo, relating to anatomical gifts, and neither parent caused the death of such child or consented to someone causing the death of such child; or

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

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

(5) "Grant awards" shall mean awards of state funds pursuant to sections 192.1010 to 192.1030;

(6) "Human cloning" shall mean the replication of a human being genetically identical to another human being;

(7) "Research project" shall mean research specified in the grant award conducted under the auspices of the institution or institutions that applied for and received such grant award pursuant to sections 192.1010 to 192.1030, regardless of whether the research is funded in whole or part by such grant award. 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 research in human development and aging, cancer, endocrine, cardiovascular, neurological, pulmonary and infectious disease, and nutrition and food safety. Such research may also include research and development on product safety and preventative care technologies.

3. No grant awards shall be paid or granted pursuant to sections 192.1010 to 192.1030 to or on behalf of an existing or proposed research project that involves, as part of the project, abortion services, destructive human research, the development of drugs or chemicals intended to be used to induce an abortion or human cloning. A research project that receives a grant award shall not share costs with another research project, person or entity not qualified to receive a grant award pursuant to sections 192.1010 to 192.1030; provided, however, the research project that receives a grant award may pay facilities and administrative costs directly allocable to such research project. A research project that receives a grant award shall maintain financial records that demonstrate strict compliance with this section. The audit conducted pursuant to section 192.1015 shall also certify compliance with this section.

4. Any taxpayer of this state or its political subdivisions shall have standing to bring suit against the department of health, its officers or employees, in a circuit court of proper venue to enforce the provisions of this section.

5. Sections 192.1010 to 192.1030 shall not be construed to permit or make lawful any conduct that is otherwise unlawful under the laws of this state.

6. All of the provisions of sections 192.1010 to 192.1025 are severable; provided, however, the provisions of section 192.1030 are not severable from the provisions of sections 192.1010 to 192.1025. If any provision of sections 192.1010 to 192.1025 is found to be invalid, unenforceable or unconstitutional, the remaining provisions of sections 192.1010 to 192.1025 shall be and remain valid. However, if any provision of section 192.1030 shall be found to be invalid, unenforceable or unconstitutional, all the provisions of sections 192.1010 to 192.1025 shall be invalid and unenforceable.

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