

JUL 24 2001

**Executive Order**  
**01-10**

*Matt Blunt*  
SECRETARY OF STATE

WHEREAS, many institutions and entities within Missouri are engaged in life sciences research; and

WHEREAS, at the start of the new century Missouri has become an international center of life sciences research; and

WHEREAS, the continued growth of life sciences research contributes to the health and economic prosperity of Missourians and better assures that Missouri and its citizens will have one bright future; and

WHEREAS, Executive Order 00-07 created an interagency task force on the life sciences; and

WHEREAS, it is now time for the State of Missouri to move forward into the twenty-first century and to become more engaged in fostering meaningful life sciences research; and

WHEREAS, in November 1998 the National Association of Attorneys General announced a national settlement with five major tobacco companies and Missouri Attorney General Jay Nixon accepted the proposed settlement on behalf of Missouri; and

WHEREAS, from the tobacco settlement monies, an amount of \$21,567,450 was appropriated for fiscal year 2002 by the General Assembly to the Office of Administration for the purpose of funding life sciences contracts and related expenses; and

WHEREAS, I, Bob Holden, as Governor of the State of Missouri, heretofore issued Executive Order 01-05 on the 9<sup>th</sup> day of February, 2001, directing the Commissioner of the Office of Administration to create within the state treasury the Healthy Families Trust Fund - Life Sciences Research Account; and

WHEREAS, I, Bob Holden, as Governor of the State of Missouri, in said Executive Order 01-05 further directed the Commissioner of the Office of Administration to receive and expend tobacco settlement money in accordance with the budget submitted to the General Assembly, as truly agreed to and finally passed in appropriation bill, House Bill 14, (91<sup>st</sup> General Assembly); and

WHEREAS, it is desirable and in the public interest to create a system which will assure that all monies within the Life Sciences Research Account are used to strengthen life sciences research in a manner which will build on present strengths in order to maximize the research capacity of the State; and

WHEREAS, it is necessary that the increased research expansion contribute to the health and economic welfare of the people of the State and that such monies be expended and administered in a prudent manner with proper and adequate fiscal controls; and

WHEREAS, life sciences research and technological innovation, as well as quality and abundant agricultural products, are intrinsically linked to the health and economic prosperity of all Missourians through application of new discoveries within the life sciences; and

WHEREAS, life science research holds promise for the preservation and enhancement of the health and quality of life of the people of Missouri through development and clinical research, including but not limited to research in human development and aging, cancer, diabetes, cardiovascular disease, neurological disease, pulmonary conditions, sickle cell anemia, infectious disease, nutrition, food safety, connective tissue disease, asthma and obesity; and

WHEREAS, there is a need to involve the citizenry of Missouri and persons knowledgeable in the life sciences in the governance of a system for life sciences research.

NOW, THEREFORE, I, Bob Holden, Governor of the State of Missouri, under the authority vested in me by the Constitution and laws of this state, hereby direct and order as follows:

### Section 1. Life Sciences Research Account

The Life Sciences Research Account within the Healthy Families Trust Fund, which was created by Executive Order 01-05, shall be used and expended pursuant to House Bill 14 (Ninety-First General Assembly), Section 14.015, for life sciences research purposes set forth in this Executive Order, except as otherwise specifically provided by the Constitution or the laws of this state.

### Section 2. Purposes

Monies in the Life Sciences Research Account shall be used strategically to enhance, in cooperation with other governmental and not-for-profit entities, the State of Missouri's capacity to serve the health and welfare of the residents of Missouri as a center of life sciences research and development by building on the success of research institutions located in Missouri and enhancing their ability to carry out their respective missions.

### Section 3. Life Sciences Research Committee

Funds in the Life Sciences Research Account shall be administered by the Commissioner of the Office of Administration ("Commissioner") based upon the recommendations of the Life Sciences Research Committee ("Committee"). The Committee shall solicit, collect and prioritize proposed research initiatives for consideration for funding by the Commissioner.

The Committee shall consist of eight appointed members, together with the Commissioner, who shall be appointed in the following manner:

- (1) The Governor shall appoint each member for a term of six years, except for the terms of the initial members. The Governor shall select the chairperson.
- (2) Two initial members of the Committee shall be appointed to two-year terms. Three initial members shall be appointed to four-year terms. The remaining three initial members shall be appointed to six-year terms. All subsequent appointees shall be appointed to six-year terms.
- (3) 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. The membership shall include representatives from the life sciences industry, business community, distinguished scientists, and other technology leaders.
- (4) No member of the Committee shall serve more than two consecutive full six-year terms on the Committee.

The Committee shall have the authority to: (i) recommend research contracts for building research capacity with input from the review panels, established pursuant to Section 4, below; (ii) recommend guidelines and requirements consistent with established federal and state policies and practices applicable to contracting, the

expenditures of funds, scientific standards, institutional licensing procedures, the reimbursement of costs, utilization of intellectual property rights, and conflicts of interest guidelines which the Commissioner may adopt; (iii) assist the Commissioner in establishing review panels to recommend and review proposals that would strengthen and enhance the research capabilities of life sciences entities and research institutions, and (iv) establish priorities for funding projects in the life sciences in a manner consistent with the health, welfare and economic prosperity of Missouri's citizens.

The members of the Committee shall receive no salary or other compensation for their services as members, but shall receive their necessary traveling and other expenses incurred while actually engaged in the discharge of their official duties.

#### Section 4. Review Panels

The Commissioner of the Office of Administration, with input from the Committee, shall establish panels to review contract proposals and make recommendations to the Committee in connection therewith. There may be established by the Commissioner, with recommendations from the Committee, a first step process by which proposals would be solicited and evaluated by a regional panel that would forward qualified and competitive proposals to the Committee.

The Commissioner may also, with input from the Committee, engage scientific review panels to which the Committee would forward proposals received through the regional review process for an evaluation and determination of their scientific quality and appropriateness.

#### Section 5. Use of Funds

The Office of Administration shall take proposals for contracts in order to increase the capacity and infrastructure for quality life sciences research in the State of Missouri and to improve the quality and quantity of life sciences research. Such life sciences research shall include: (a) basic research, including the discovery of new knowledge; (b) translational research, including translating knowledge into a usable form; and (c) developmental research and clinical research in the life sciences.

#### Section 6. Contract Proposals

The Request for Proposals shall be designed by the Office of Administration in consultation with the Committee and shall contain information necessary to determine the potential benefits of contracts to be awarded, as well as other information deemed necessary for the administration of the Life Sciences Research Account. The contract awards shall be in accordance with Chapter 34 RSMo.

Contract awards shall only be made to public and/or private not for profit academic, research health care, or other institutions or organizations located in Missouri.

Contract applications and contract awards shall be processed in compliance with chapter 610, RSMo.

The Commissioner shall not approve a contract award unless he or she makes specific written findings that the expenditure of funds for such contracts shall be in compliance with Sections 6.1 to 6.4 of this Executive Order.

- 6.1 No contract awards shall be paid, given or used to subsidize in whole or in part:
- (1) Abortion services; or
  - (2) Development of drugs or chemicals intended to be used to induce an abortion; or
  - (3) Human cloning; or
  - (4) Prohibited human research.

6.2 For purposes of this section, the following terms mean:

- (1) "Abortion services", 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 vivo, the same as an unborn child as defined in section 188.015, RSMo, and if in vitro, a human being at any of the stages of biological development of an unborn child from conception or inception onward;
- (3) "Conception" the same as defined in section 188.015 RSMo;
- (4) "Facilities and administrative costs", those costs that are incurred for common or joint objectives and therefor cannot be identified readily and specifically with a particular research project or any other institutional activity;
- (5) "Contract awards", agreement to pay for research on other provisions in the contract pursuant to this Executive Order;
- (6) "Human cloning", the replication of a human being genetically identical to another human being;
- (7) "Prohibited human research", research in a proposed research project in which there is the taking or utilization of the organs, tissue or cellular material of a :
  - (a) Deceased child, unless consent is given in the manner provided in sections 194.210 to 194.290, RSMo, relating to anatomical gifts, and neither parent cause the death of such child or consented to another person causing the death of such child;
  - (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;
- (8) "Research project", research specified in the contract award conducted under the auspices of the institution, institutions, entity or entities that applied for and received such contract award pursuant to this Executive Order, regardless of whether the research is funded in whole or part by such contract award. Such research shall include basic research, including the discovery of new knowledge; translational research, including translating knowledge into a useable form; and (c) developmental research and clinical research in the life sciences.

6.3 No contract awards shall be paid or given pursuant to this Executive Order to or on behalf of an existing or proposed research project that involves, as part of the project, abortion services, development of drugs or chemicals intended to be used to induce an abortion, human cloning or prohibited human research. A research project that receives a contract award shall not share costs with another research project, person or entity not qualified to receive a contract award pursuant to this Executive Order; provided, however, the research project that receives a contract award may pay facilities and administrative costs directly allocable to such research project. A research project that receives a contract award shall maintain financial records that demonstrate strict compliance with this section. The audit conducted pursuant to section 8 of this Executive Order shall also certify compliance with this section.

- 6.4 The contract proposal shall describe in detail the proposed research project and how the research project shall be conducted in compliance with the requirements of Section 6.1 to 6.4 of this Executive Order.

#### Section 7. Administrative Support

Administrative support for the Committee shall be provided by the Office of Administration, which shall include: facilities, equipment, administrative and technical support services and administrative staff.

#### Section 8. Audits and Reports

The Office of Administration shall make provision for and secure from the State Auditor 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 Account. The Office of Administration will make copies of each audit publicly available.

Every three years, the Commissioner and the Committee shall prepare a comprehensive report assessing their work and progress. Such assessment report shall analyze the impact of the research performed, and shall be provided to the Governor and members of the General Assembly, and shall be publicly available.

#### Section 9. Cost Reimbursement

Contracts made by the Commissioner may provide for the reimbursement of cost. Reimbursement of particular costs will be based on guidelines established in OMB Circular A-21 section C which provides as follows: Allowable costs include those costs that: (a) are reasonable; (b) are allocable to the project under the recipients' standard accounting practices; (c) are given consistent treatment through application of those generally accepted accounting principles appropriate to the circumstances; and (d) conform to any limitations or exclusions set forth in these principles or in the contract as to types or amounts of cost items.

No payment may be made unless provided for in the contract agreement. In general, costs should be directly necessary to conduct the agreed upon research or to meet the provisions set forth in the contract.

#### Section 10. Publication and Use of Research Results

Contract recipients have an obligation to preserve academic and research freedom, to ensure timely disclosure of their research findings to the scientific community, including through publication 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 contract award. The property rights including intellectual property rights of institutions or organizations receiving contract awards pursuant to this Executive Order shall be in compliance with The Patent and Trademark Law Amendments Act -- Public Law 96-517, 1980 ( Bayh - Dole Act) as amended, and as codified in Title 35 United States Code Section 200 - 212, as amended, and 37 Code of Federal Regulations Part 401, as amended. The Commissioner may adopt reasonable guidelines to ensure that contracts are awarded in a manner which is in the public interest.

#### Section 11. Effective Date and Effectiveness

The provisions of this Executive Order shall become effective upon the date of its issuance set forth below. The provisions of this Executive Order shall continue in effect until superceded or changed by constitutional amendment, by law or by a subsequent Executive Order.



IN WITNESS WHEREOF, I have hereunto set my hand and caused to be affixed the Great Seal of the State of Missouri, in the City of Jefferson, on this 23<sup>rd</sup> day of July, 2001.

*Bob Holden*

BOB HOLDEN  
GOVERNOR

ATTEST:

*Matt Blunt*

MATT BLUNT, SECRETARY OF STATE