



2005-6

Executive Order Creating the Illinois Regenerative Institute for Stem Cell Research

WHEREAS, millions of Illinoisans and their families suffer through debilitating diseases and injuries, and these conditions place enormous emotional and financial stress on the people afflicted and all those who care for them; and

WHEREAS, in August 2001, the President announced a policy limiting federal funding for research on embryonic stem cell lines; and

WHEREAS, several states have taken their own independent action in pursuit of developing better treatments and finding cures by implementing or proposing public funding initiatives for the development of embryonic stem cell research in their states; and

WHEREAS, the State of Illinois should maximize the use of state research funds by giving priority to stem cell research that has the greatest potential for therapies and cures that cannot or are unlikely to receive sufficient federal funding; and

WHEREAS, medical research advances that lead to better treatments of diseases and ultimately cures will help reduce long-term health care costs on Illinois taxpayers; and

THEREFORE, I HEREBY ORDER THE FOLLOWING:

Illinois Department of Public Health (Grant program/ Rulemaking)

The Director of the Illinois Department of Public Health shall develop an Illinois Regenerative Medicine Institute (IRMI) program within the department that will provide for the awarding of grants to medical research facilities for the development of finding treatments and cures from stem cell research.

The Department of Public Health shall adopt rules for the issuance and administration of grants authorized by this Executive Order. All eligible grant recipients shall comply with all terms and conditions of the Department prior to acceptance of such awards.

Stem Cell Research Policy & IRMI Functions

All rules adopted by the Department shall be consistent with the policies and functions of the Illinois Regenerative Medicine Institute (IRMI) program as set forth below:

- 1) The Department of Public Health shall establish the IRMI program to make grants and loans for stem cell research to study therapies, protocols, medical procedures, possible cures for, and potential mitigations of, major diseases, injuries, and orphan diseases; to support all stages of the process of developing cures, from laboratory research through successful clinical trials; to establish the appropriate regulatory standards and oversight bodies for research and facilities development.
- 2) The IRMI program shall provide funding for stem cell research that involves adult stem cells, cord blood stem cells, pluripotent stem cells, totipotent stem cells, progenitor cells, the product of somatic cell nuclear transfer or any combination of those cells.
- 3) No funds authorized or made available under the IRMI program shall be used for research involving the reproductive cloning of a human being, fetuses from induced abortions or to create embryos through the combination of gametes solely for the purpose of research. As used in this Executive Order, "cloning

of a human being" means asexual human reproduction by implanting or attempting to implant the product of nuclear transplantation into a woman's uterus to initiate a human pregnancy.

4) No funds shall be awarded to any person who knowingly, for valuable consideration, purchases or sells embryonic or cadaveric fetal tissue for research purposes. For the purposes of this paragraph, payment of customary medical charges for the removal, processing, disposal, preservation, quality control, storage, transplantation, or implantation of the tissue does not constitute valuable consideration. This paragraph does not prohibit reimbursement for removal, storage, or transportation of embryonic fetal tissue for research purposes pursuant to this Executive Order.

5) The Department shall issue an annual report to the Governor, and the appropriate appropriations committee of the General Assembly that sets forth grants awarded, grants in progress, research accomplishments, and future program directions.

Grantee Requirements & Conditions

Medical and scientific accountability standards.

All eligible grantees shall comply with all terms and conditions of the Department rules which shall include, but not be limited to, the specific requirements and conditions as set forth below prior to acceptance of any such grant awards.

(1) Informed consent. Standards for obtaining the informed consent of research donors, patients, or participants initially shall be generally based on the requirements at 45 CFR 46.116 for all research funded by the National Institutes of Health and consistent with the Guidelines for Human Embryonic Stem Cell Research issued by the National Academies of Sciences.

(2) Controls on research involving humans. Standards for the review of research involving human subjects shall be generally based on the policies adopted at 45 CFR 46 for all research funded by the National Institutes of Health.

(3) Limitations on payments for cells. Department rules shall limit payments for the purchase of stem cells or stem cell lines to reasonable payment for removal, processing, disposal, preservation, quality control, storage, transplantation, implantation, or legal transaction or other administrative costs associated with these medical procedures and shall specifically include any required payments for medical or scientific technologies, products, or processes for royalties, patent, licensing fees, or other costs for intellectual property. Department rules shall be consistent with the Guidelines for Human Embryonic Stem Cell Research issued by the National Academies of Sciences.

(4) Patient privacy laws. Standards shall ensure compliance with State and federal patient privacy laws.

(5) Time limits for obtaining cells. Standards shall set a limit on the time during which cells may be extracted from blastocysts, which shall initially be 8 to 12 days after cell division begins, not counting any time during which the blastocysts or cells have been stored frozen.

(6) All grants and loan awards issued by the institute shall include intellectual property provisions that provide protections and incentives to encourage both the discovery and development of new knowledge and its transfer for the public benefit. It is the policy and objective of the institute to promote the utilization of intellectual property arising from program-supported research or development; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that intellectual property is used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to ensure that the State obtains proportionate rights in institute-supported intellectual property; to protect the public against nonuse or unreasonable use of such intellectual property; and to minimize the costs of administering policies in this area.

Severability

If any provision of this Executive Order or its application to any person or circumstance is held invalid by any court of competent jurisdiction, this invalidity does not affect any other provision or application of this Executive Order which can be given effect without the invalid provision or application. To achieve this purpose, the provisions of this Executive Order are declared to be severable.

Effective Date

This Executive Order shall become effective upon filing with the Secretary of State.

ROD R. BLAGOJEVICH,
Governor

Issued by Governor: July 12, 2005

Filed with Secretary of State: July 12, 2005