

**INITIATIVE FINANCIAL INFORMATION STATEMENT**  
**Funding of Embryonic Stem Cell Research**

**SUMMARY OF INITIATIVE FINANCIAL INFORMATION STATEMENT**

Based on information provided through public workshops and information collected through staff research, the Financial Impact Estimating Conference principals expect that the proposed amendment will have the following financial impacts:

- State-supported research costs will increase. The proposed constitutional amendment requires the state to annually spend \$20 million for ten years to provide grants for embryonic stem cell research. Because the amendment is self-executing, costs incurred by the Department of Health to administer the grant program are assumed to be included within the \$20 million appropriated each year.
- There were no other probable financial impacts on state and local governments identified by the conference.

**FINANCIAL IMPACT STATEMENT**

This amendment requires the state to spend \$20 million a year for ten years.

## I. SUBSTANTIVE ANALYSIS

### A. Proposed Amendment

#### Ballot Title:

Funding of Embryonic Stem Cell Research

#### Ballot Summary:

This amendment appropriates \$20 million annually for ten fiscal years for grants by the Department of Health to Florida nonprofit institutions to conduct embryonic stem cell research using, or using derivatives of, human embryos that, before or after formation, have been donated to medicine under donor instructions forbidding intrauterine embryo transfer. An embryo is "donated to medicine" only if given without receipt of consideration other than cost reimbursement and compensation for recovery of donated cells.

#### 1) Statement and Purpose:

The purpose of the amendment is to require the Florida Legislature to annually fund for ten years grants to nonprofit institutions to conduct embryonic stem cell research.

#### 2) Amendment of Florida Constitution:

Article X of the Florida Constitution is hereby amended by inserting at the end thereof the following section:

##### **Funding of embryonic stem cell research.**

(a) There is hereby appropriated from the General Revenue Fund to the Department of Health the sum of \$20 million in each of the ten fiscal years beginning with the year in which the amendment is adopted. With such funds the Department of Health shall make grants for embryonic stem cell research using, or using the derivatives of, human embryos that, before or after formation, have been donated to medicine under donor instructions forbidding intrauterine embryo transfer.

(b) For this purpose, an embryo is "donated to medicine" if and only under conditions that satisfy applicable requirements for informed consent and do not involve financial inducement to any donor, the persons from whose cells the embryo originates give the embryo to another under written instructions that the recipient shall use the embryo in biomedical research or therapy. "Financial inducement" includes any valuable consideration but excludes (1) reimbursement for reasonable costs incurred in connection with a donation, and (2) reasonable compensation to a donor from whom an oocyte is recovered, and to the donor of any other cell recovered by an invasive procedure, for the preparation for and time, burden, and risk of such recovery.

(c) The funds appropriated hereby shall be granted to nonprofit academic and other research institutions situated within the state. Grantees shall be chosen on the basis of a recommended ordering of applications by scientific merit as reckoned in a peer review process by disinterested experts in the relevant fields.

(d) This provision shall be self-executing and effective immediately upon adoption. This appropriation shall be nonlapsing such that any portion of a yearly appropriation not distributed shall accumulate for distribution in subsequent years. The Department of Health is authorized to promulgate administrative rules for the implementation hereof.

#### 3) Effective Date:

This amendment will be effective on the date it is approved by the electorate.

### B. Effect of Proposed Amendment

According to Floridians for Stem Cell Research and Cures, Inc., their purpose in sponsoring the constitutional amendment is as follows:

- To provide grants for embryonic stem cell research in this state with anticipation that sustained funding over a period of years will provide for an understanding of the root causes of afflictions for which no cures are presently known.
- To sustain research that will ultimately lead to an alleviation of human suffering from medical conditions such as diabetes, cardiovascular diseases, autoimmune diseases, osteoporosis, cancer, Alzheimer's, Parkinson's, burns (severe), spinal cord injuries, birth defects and other conditions.
- To reduce this state's disease burden, while advancing scientific endeavors in this state.
- To stimulate economic development in the state, particularly in the biotechnology field, through investment biomedical research in Florida.
- To increase Florida's competitive edge by attracting leading researchers in the field of embryonic stem cell research to this state.
- To maximize the already substantial investment in modern biomedical research facilities and existing infrastructure at nonprofit academic and research institutions by funding biomedical research in the field of embryonic stem cells.
- To support research at nonprofit academic and other research institutions in the state.<sup>1</sup>

## Background

### *Stem Cells and Diseases*

Stem cells are unique and unspecialized cells. The purpose of stem cells in the adult body is to replace cells normally lost because of age, injury or disease. Two properties that make stem cells unique from other cells:

1. Stem cells can divide thousands of times without error and without breaking down. Scientists can cause one stem cell to produce hundreds of identical stem cells in what is called a line.
2. Stem cells can differentiate into a variety of different cells. Scientists can induce stem cells to become cells with special functions, such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.<sup>2</sup>

Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). There are differences between adult and embryonic stem cells. Adult stem cells are limited in the variety of cells they can differentiate into and generally only develop into the cell types of the tissue from which they were isolated.<sup>3</sup> Embryonic stem cells are pluripotent, that is, capable of differentiating into one of many cell types. After an egg is fertilized, it begins to divide from one cell into two, then from two cells into four, and so on. In the first few divisions, each embryo cell contains the ability to make all the cells in the human body. As the embryo continues to divide, the cells begin to specialize into particular organ cells.

Embryonic stem cells offer the possibility of a renewable source of replacement cells and tissues to treat a myriad of diseases, conditions, and disabilities including Parkinson's and Alzheimer's diseases, spinal cord injury, stroke, burns, heart disease, diabetes, osteoarthritis and rheumatoid

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<sup>1</sup> Bernard Siegel, electronic mail to conference principals, November 17, 2006.

<sup>2</sup> Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. Available at <[www.bioethics.umn.edu](http://www.bioethics.umn.edu)>.

<sup>3</sup> In *Stem Cell Basics*. [World Wide Web site] Bethesda, MD. National Institutes of Health, U.S. Department of Health and Human Services, 2006. Available at <<http://stemcells.nih.gov/index.asp>>.

arthritis. Scientists have been able to conduct experiments with human embryonic stem cells, however, only since 1998.<sup>4</sup> Thus, although embryonic stem cells are thought to offer potential cures and therapies for many devastating diseases, research using them is still in its early stages.

### *Federal Regulations*

The Federal Register announcement National Institutes of Health Guidelines for Research Using Human Pluripotent Stem Cells, published August 15, 2001, Section II B, titled "Utilization of Human Pluripotent Stem Cells Derived from Human Fetal Tissue," governs human embryonic stem cell research. The guidelines establish procedures for investigators or institutions requesting National Institutes of Health (NIH) funds for research using human pluripotent stem cell lines derived from embryos or fetal tissue. The NIH maintains the official registry of stem cell lines meeting these criteria. The notice also outlines the procedures NIH will use to implement oversight of this process. Section III, titled "Areas of Research Involving Human Pluripotent Stem Cells That Are Ineligible for NIH Funding," governs both human embryonic stem cell and human embryonic germ cell research.<sup>5</sup> Individual states have the authority to pass laws to permit human embryonic stem cell research using state funds. Unless Congress passes a law that bans it, states may pay for research using human embryonic stem cell lines that are not eligible for federal funding.

In November 2001, President George W. Bush created The President's Council on Bioethics. The council's mission is to advise the president on bioethical issues that may emerge as a consequence of advances in biomedical science and technology. The council is authorized to study ethical issues connected with specific technological activities, such as embryo and stem cell research, assisted reproduction, cloning, uses of knowledge and techniques derived from human genetics or the neurosciences, and end of life issues. The council may also study broader ethical and social issues not tied to specific technology, such as questions regarding the protection of human subjects in research, the appropriate uses of biomedical technologies, the moral implications of biomedical technologies, and the consequences of limiting scientific research.<sup>6</sup>

### *The James and Esther King Biomedical Research Program*

The 1999 Legislature established the Lawton Chiles Endowment Fund (chapter 99-167, Laws of Florida), through which the state uses funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, Florida Statutes, establishes the James and Esther King Biomedical Research Program within the Department of Health funded from transfers from the General Revenue Fund (\$6 million) and interest earnings from the Lawton Chiles Endowment Fund (\$3.5 million). Funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. Actual administrative expenses may not exceed 15 percent of the total funds available to the program in any given year. Administrative expenditures for Fiscal Year 2004-2005 were 5.6 percent; expenditures for Fiscal Year 2005-06 were approximately 7 percent. The department estimates that expenditures for the current fiscal year will be approximately 12 percent.

Section 215.5602(3), Florida Statutes, creates a nine-member Biomedical Research Advisory Council in the department. The council must advise the Secretary of Health as to the direction and scope of the biomedical research program. The research conducted may include stem cell related

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<sup>4</sup> In *Stem Cell Information* [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2006. Available at <<http://stemcells.nih.gov/info/health>>.

<sup>5</sup> In *Stem Cell Information* [World Wide Web site]. Bethesda, MD: National Institutes of Health, U.S. Department of Health and Human Services, 2006. Available at <<http://stemcells.nih.gov/info/faqs.asp>>.

<sup>6</sup> Executive Order 13237, November 28, 2001.

research. However, the state supports research on only adult stem cell and placenta or cord blood stem cells.

#### *Florida Center for Universal Research to Eradicate Disease*

Florida's Center for Universal Research to Eradicate Disease (CURED) was created by the Florida Legislature in its 2004 Regular Session. Section 381.855, Florida Statutes, established the program and created an advisory council to provide policy recommendations to the Legislature. The CURED seeks to coordinate, improve, expand and monitor all biomedical research programs within the state, facilitate funding opportunities, and foster improved technology transfer of research findings into clinical trials and widespread use. It seeks to promote research programs that identify cures to cancer, heart and lung disease, diabetes, autoimmune disorders and neurological disorders, including Alzheimer's disease, epilepsy, and Parkinson's disease. The program is appropriated \$250,000 from the annual administrative expenses allocated to the James and Esther King Biomedical Research program.

As part of the enabling legislation for the CURED, the program is charged with holding an annual biomedical technology summit in Florida. The first summit was held August 1, 2006.<sup>7</sup> The CURED is also directed to monitor the supply and demand needs of researchers relating to stem cell research and other types of human tissue research. The CURED has not started monitoring the supply and demand of stem cells in Florida and does not plan to in the immediate future.<sup>8</sup>

#### *Institutional Review Boards*

The Department of Health (DOH) has two institutional review boards (IRBs) that review all state-funded research involving human subjects, including research involving stem cells under section 381.86, Florida Statutes. The Secretary of Health appoints board members, chairs, and co-chairs to the DOH institutional review boards. The department maintains compliance with all applicable federal regulations and guidance. The DOH IRBs meet twice a month.

DOH currently staffs four legislatively-created research programs with advisory councils: The James and Esther King Biomedical Research Program, the Florida Cancer Center, the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, and the Florida Center for Universal Research to Eradicate Disease. According to the department, the two IRBs are at maximum capacity for the research programs indicated above, and adding another research program would require another IRB.

## **II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

Section 100.371, Florida Statutes, requires that the Financial Impact Estimating Conference “. . . complete an analysis and financial impact statement to be placed on the ballot of the estimated increase or decrease in any revenue or costs to state or local governments resulting from the proposed initiative.”

As part of determining the fiscal impact of this proposed amendment, the Financial Impact Estimating Conference (FIEC) principals held three public meetings—October 25, November 6 and November 15, 2006.

### **A. FISCAL ANALYSIS**

The fiscal impact summary for this proposed constitutional amendment is based on independent research, testimony before the FIEC public workshops, written statements from the sponsor and opponents of the initiative, responses from the Department of Health

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<sup>7</sup> Summit Proceedings Report, Florida Center for Universal Research to Eradicate Disease, November 2, 2006. Available at <<http://www.doh.state.fl.us/execstaff/biomed/summit.html>>.

<sup>8</sup> Annual Report of the Advisory Council of the Florida Center for Universal Research to Eradicate Disease, 2006.

regarding fiscal impacts, and discussions among the FIEC principals and other professional staff. Based on this information, the FIEC principals expect that the proposed constitutional amendment will have the following financial effects on state government.

- There is no direct impact on state or local government revenues.
- State-supported research costs will increase. The proposed constitutional amendment requires the state to annually spend \$20 million for ten years to conduct embryonic stem cell research, totaling \$200 million over the life of the program. Also, the Department of Health will incur costs for administering the program, expected to range from \$1.0 million to \$2.0 million per year.
- State-funded entities may benefit as recipients of the grants, but by what amount (if any) is impossible to determine in advance.
- Because state dollars are limited by statutory authorization and economic conditions, the requirement to spend these dollars on a specified program may result in reductions to existing programs or an increase in taxes. At this time, it is impossible to determine.
- Savings to state and local government health and insurance programs is speculative and cannot be determined. In its draft October 2006 Scientific Strategic Plan, the California Institute of Regenerative Medicine (CIRM) stated “given the time (8–10 years) and expense (\$800 million) . . . it is unlikely that CIRM will be able to fully develop stem cell therapy for routine clinical use during the ten years of the plan.”<sup>9</sup> Moreover, two leading British scientists, Professor Colin McGuckin (a specialist in regenerative medicine at Newcastle University) and Dr. Stephen Minger (director of the Stem Cell Biology Laboratory at King’s College) indicate that any potential cures from embryonic stem cell research are many years away and that considerably more “fundamental research” is necessary before embryonic stem cells will be able to help patients.<sup>10</sup> Based on these comments, it is impossible to determine any savings to state- or locally-funded health and insurance programs within the life of the program.

## B. FISCAL IMPACT ON STATE AND LOCAL GOVERNMENTS:

### 1. Revenues:

There is no direct financial impact to state and local revenues.

### 2. Expenditures:

The state will be required to appropriate \$20 million from the General Revenue Fund each year for ten years. Because the amendment is self-executing, costs incurred by the Department of Health to administer the grant program are assumed to be included within the \$20 million appropriated each year. The Department of Health estimates the following administrative expenses. However, fewer number of grant applications received or number of grants awarded may reduce the administrative costs.

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<sup>9</sup> Available at <[http://www.cirm.ca.gov/meetings/pdf/2006/10/Strat\\_Plan\\_100406.pdf](http://www.cirm.ca.gov/meetings/pdf/2006/10/Strat_Plan_100406.pdf)>.

<sup>10</sup> LifeNews.com, August 1, 2006 [World Wide Web site]. Available at <<http://www.lifenews.com/bio1682.html>>

**Stem Cell Research Grant Program  
(Based on \$20 million annual appropriation)**

<b>Estimated Expenditures</b>	<b>1st Year</b>	<b>2nd Year</b>
<b>Salaries<sup>1</sup></b>		
1 Program Administrator @ \$55,000	\$75,075	\$77,327
1 Program Assistant @ \$35,000	\$47,775	\$49,208
1 IRB Admin. Assistant @ \$40,000	\$54,600	\$56,238
0.5 Senior Attorney @ \$58,000	\$39,585	\$40,773
0.5 Senior Attorney @ \$58,000	\$39,585	\$0
0.5 Legal Secretary @ \$35,000	\$27,300	\$28,119
<b>Subtotal</b>	<b>\$283,920</b>	<b>\$251,665</b>
<b>Expense</b>		
1 Professional, w/ maximum travel	\$23,393	\$20,195
1 Professional, w/ medium travel	\$20,753	\$17,476
1 Professional, w/ limited travel	\$18,026	\$14,667
0.5 Professional, w/ limited travel	\$13,060	\$9,551
0.5 Professional, w/ limited travel	\$13,060	\$9,551
0.5 Support Staff, w/ no travel	\$9,948	\$6,346
3 Advisory Council Meetings	\$23,964	\$24,683
2 Advisory Council Meetings, teleconference	\$1,500	\$1,545
IRB expense <sup>2</sup>	\$30,250	\$31,158
Professional development	\$10,000	\$10,300
Program marketing, info. dissemination	\$5,000	\$5,150
Annual Report	\$20,000	\$20,600
Honorarium, peer review <sup>3</sup>	\$113,000	\$56,500
Honorarium, quality assurance site visits <sup>4</sup>	\$30,000	\$60,000
Technical services contract <sup>5, 6</sup>	\$1,034,021	\$599,750
<b>Subtotal</b>	<b>\$1,365,974</b>	<b>\$887,471</b>
<b>Total Estimated Expenditures</b>	<b>\$1,649,894</b>	<b>\$1,139,136</b>

<sup>1</sup> Salaries are computed w/ 30% fringe, 5% administrative fee, and 3% base salary increase for second year.

<sup>2</sup> Mostly additional education for members and office supplies.

<sup>3</sup> Receiving 130 applications in year one (conducting two funding cycles) & 65 applications in year two.

<sup>4</sup> Honorarium for quality assurance site visits increases with the number of active grants.

<sup>5</sup> Estimates based on James & Esther King and Bankhead-Coley program costs. First year is higher for one time only information systems development cost and conducting two funding cycles in one year.

<sup>6</sup> Estimates based on using current contractor. Costs may increase with a different contractor.