



# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. HOUSE PRINCIPLES ANALYSIS:

Provide limited government—The bill appropriates \$20 million annually over a 10-year period to fund stem cell research.

### B. EFFECT OF PROPOSED CHANGES:

#### Present Situation

##### *Stem Cell Research*

According to the National Institutes of Health, stem cells have two unique characteristics that distinguish them from other types of cells:<sup>1</sup> (1) stem cells are unspecialized, renewing over long periods of time through cell division and (2) under certain conditions, stem cells may be induced to become cells with special functions, known as differentiation, such as beating cells of the heart muscle or the insulin-producing cells of the pancreas.

Embryonic and adult stem cells are the two primary types of stem cells that are used for scientific research. Embryonic stem cells are generally generated from embryos that develop from eggs fertilized *in vitro*. The inner cell mass of the embryo is added to a “nutrient broth” within a laboratory culture dish, allowing the inner cell mass to proliferate; the embryo is then discarded. Embryonic stem cells that proliferate in cell culture for six months or more without differentiating are known as “pluripotent,” which means the stem cells are potentially able to differentiate into many cell types. This desirable attribute is known as “plasticity.”

Embryos for embryonic stem cell research may be obtained from other, more controversial sources, including aborted fetuses and embryos created through somatic cell nuclear transfer (SCNT), otherwise known as “therapeutic cloning.” Therapeutic cloning involves removing the nucleus of an unfertilized egg cell, replacing it with the material from the nucleus of a “somatic cell” (such as a skin, heart, or nerve cell), and stimulating the cell to begin dividing. Once the cell begins dividing, stem cells can be extracted 5-6 days later and used for research.<sup>2</sup> The embryo is then discarded.

Embryonic stem cells may, in the future, have significant value in scientific research, including the generation of cells and tissues for cell-based therapies, i.e., replacing ailing or destroyed tissue. These therapies may include treatment of:

- Chronic heart disease through the implantation of heart muscle cells;
- Diabetes through the implantation of insulin-producing cells; and
- Parkinson’s Disease through the implantation of dopamine-producing neurons.

Adult stem cells are undifferentiated cells found among differentiated cells in a tissue or organ. An adult stem cell may renew itself and differentiate to produce the major specialized cell types of the tissue or organ. There are a number of types of adult stem cells, including amniotic, bone marrow, liver, neuronal, and umbilical cord blood. Adult stem cells generally generate the cell types of the tissue in which they reside. However, recent research has identified pluripotent stem cells within amniotic fluid, bone marrow, and umbilical cord blood.<sup>3</sup>

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<sup>1</sup> Except where otherwise noted, this section is substantially derived from *Stem Cell Information, The official National Institutes of Health resource for stem cell research* (viewed April 5, 2007) <http://stemcells.nih.gov/staticresources/info/basics/StemCellBasics.pdf>

<sup>2</sup> Somatic Cell Nuclear Transfer (Therapeutic Cloning) (viewed April 6, 2007)

<http://www.aamc.org/advocacy/library/research/res0003.htm>.

<sup>3</sup> See, e.g., Christian Catalano, *Stem cells take growth of heart tissue a step closer* (viewed April 5, 2007)

<http://www.theage.com.au/news/world/stem-cells-take-growth-of-heart-tissue-a-step-closer/2007/04/02/1175366160708.html>;

While treatments using embryonic stem cells have resulted in limited success in animals,<sup>4</sup> treatments on humans using adult stem cells have resulted in meaningful improvement for conditions such as Parkinson's disease,<sup>5</sup> multiple sclerosis,<sup>6</sup> and lupus,<sup>7</sup> among others.

#### *Stem Cell Research at the Federal Level*

On August 9, 2001, President George W. Bush announced his decision to narrow the federal funding of research using embryonic stem cell lines to specific lines. A "stem cell line" is a population of cells that reproduce themselves over a long period of time *in vitro*. Specifically, stem cell research is allowed on existing stem cell lines that were derived:

- With the informed consent of the donors;
- From excess embryos created solely for reproductive purposes; and
- Without any financial inducement to the donors.<sup>8</sup>

At the time of the President's decision, approximately 60 stem cell lines qualified under the criteria noted above. Recent studies have suggested that these lines have become contaminated with non-human molecules.<sup>9</sup>

In 2006, an attempt by Congress to authorize embryonic stem cell research outside existing lines was vetoed by the President.<sup>10</sup>

#### *Stem Cell Research in Florida*

In Florida, biomedical research dollars are awarded through at least nine different programs.<sup>11</sup> Of these programs, significant funding is providing for the James and Esther King Biomedical Research Program

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(discussing British scientists who used bone marrow stem cells to grow the same cells present in heart valves); Paolo De Coppi et al., *Isolation of amniotic stem cell lines with potential for therapy*, 25 *Nature Biotechnology* 100 (2007) (concluding that amniotic stem cells are pluripotent and hold potential for a variety of therapeutic applications); and Ryan Carlin et al., *Expression of early transcription factors Oct-4, Sox-2 and Nanog by porcine umbilical cord (PUC) matrix cells*, 4 *Reproductive Biology and Endocrinology* 8 (2006) (concluding that stem cells obtained from umbilical cord blood contain the three transcription factors expressed at high levels in embryonic stem cells; thus, umbilical cord blood stem cells have properties of primitive pluripotent stem cells).

<sup>4</sup> See, e.g., UCI researchers use human embryonic stem cells to create new nerve insulation tissue that can aid spinal cord repair (viewed April 6, 2007) [http://today.uci.edu/news/release\\_detail.asp?key=1242](http://today.uci.edu/news/release_detail.asp?key=1242) ("researchers have used human embryonic stem cells to create new insulating tissue for nerve fibers in a live animal model – a finding that has potentially important implications for treatment of spinal cord injury and multiple sclerosis"). But see, e.g., Adult human neural stem cell therapy successful in treating spinal cord injury (viewed April 6, 2007) [http://today.uci.edu/news/release\\_detail.asp?key=1383](http://today.uci.edu/news/release_detail.asp?key=1383) (detailing research at UC Irvine that used adult neural stem cells to successfully regenerate damaged spinal cord tissue and improve mobility in mice).

<sup>5</sup> See, e.g., <http://commerce.senate.gov/hearings/witnesslist.cfm?id=1268> (viewed April 6, 2007) (containing a webcast of a 2004 meeting of the U.S. Senate Committee on Commerce, Science, & Transportation regarding adult stem cell research, including testimony of Dr. Dennis Turner, whose Parkinson's Disease was successfully treated using adult neural stem cells).

<sup>6</sup> See, e.g., Saccardi R et al., *Autologous HSCT for severe progressive multiple sclerosis in a multicenter trial: impact on disease activity and quality of life*, 105 *Blood* 2601 (2005) (concluding that bone marrow stem cell treatment is able to induce a prolonged clinical stabilization in severe progressive MS patients, resulting in both sustained treatment-free periods and quality of life improvement).

<sup>7</sup> See, e.g., Burt RK et al., *Nonmyeloablative hematopoietic stem cell transplantation for systemic lupus erythematosus*, 295 *Journal of the American Medical Association* 527 (2006) (concluding that an infusion of bone marrow stem cells resulted in amelioration of disease activity, improvement in serologic markers, and either stabilization or reversal of organ dysfunction).

<sup>8</sup> Fact Sheet: Embryonic Stem Cell Research (viewed April 5, 2007) <http://www.whitehouse.gov/news/releases/2001/08/20010809-1.html>.

<sup>9</sup> See, e.g., *Current human embryonic stem cell lines contaminated UCSD/Salk team finds* (viewed April 5, 2007) [http://www.eurekalert.org/pub\\_releases/2005-01/uoc--che011805.php](http://www.eurekalert.org/pub_releases/2005-01/uoc--che011805.php).

<sup>10</sup> Message to the House of Representatives (viewed April 5, 2007) <http://www.whitehouse.gov/news/releases/2006/07/20060719-5.html>.

<sup>11</sup> ss. 215.5601 (Lawton Chiles Endowment Fund); 215.5602 (James and Esther King Biomedical Research Program); 381.853 (Florida Center for Brain Tumor Research); 381.855 (Florida Center for Universal Research to Eradicate Disease); 381.92 (Florida Cancer Council); 381.922 (William G. "Bill" Bankhead, Jr., and David Coley Cancer research Program); 430.501 (Alzheimer's Disease Advisory Council); 1004.445 (Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute); and 1004.435, F.S. (Cancer Control and Research Advisory Council).

(\$9.5 million); the William G. "Bill" Bankhead, Jr., and David Coley Cancer research Program (\$9 million); and the Johnnie B. Byrd, Sr. Alzheimer's Center and Research Institute (\$15 million). In addition to these biomedical research grant programs, another 16 advisory groups and councils are given statutory responsibilities for programs involving medical research.<sup>12</sup>

In particular, the Florida Center for Universal Research to Eradicate Disease is tasked with coordinating, improving, expanding, and monitoring all biomedical research programs within the state, facilitating funding opportunities, and fostering improved technology transfer of research findings into clinical trials and widespread public use.<sup>13</sup>

Of the biomedical research grant programs in Florida, none, by law, specifically designate grants for stem cell research, whether embryonic or adult.

#### *Stem Cell Research in Other States*

A number of states have recently funded stem cell research, varying by the amount funded and the restrictions placed on the use of the funds.<sup>14</sup> These states include the following:

**California.** On November 2, 2004, the voters of California approved Proposition 71,<sup>15</sup> which authorized an average of \$295 million per year in bonds over a 10-year period to fund stem cell research. Priority is given to stem cell research that "has the greatest potential for therapies and cures, specifically focused on pluripotent stem cell and progenitor cell research" that are unlikely to receive sufficient federal funding.<sup>16</sup> The bond proceeds may not be used for funding for human reproductive cloning.

**Connecticut.** In June 2005, Governor Jodi Rell signed Senate Bill 934, creating the Stem Cell Research Fund to provide grants for embryonic and human adult stem cell research.<sup>17</sup> The bill appropriated \$100 million through June 30, 2015.<sup>18</sup> According to the Connecticut Department of Public Health, on November 21, 2006, \$19.78 million was awarded for 21 stem cell research proposals.<sup>19</sup> In addition, the bill prohibits (1) engaging or assisting, directly or indirectly in the cloning of a human being; (2) implanting human embryos created by nuclear transfer into a uterus or a device similar to a uterus; or (3) facilitating human reproduction through clinical or other use of human embryos created by nuclear transfer. "Cloning of a human being" is defined to mean "inducing or permitting a replicate of a living human being's complete set of genetic material to develop after gastrulation commences."<sup>20</sup>

**Illinois.** In July 2005, Governor Rod Blagojevich issued Executive Order 2005-6, directing the Illinois Department of Public Health to develop an Illinois Regenerative Medicine Institute program within the department to award grants to medical research facilities to develop treatments and cures from stem

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<sup>12</sup> ss. 385.210 (Arthritis Prevention Education); 385.203 (Diabetes Advisory Council); 385.202 (Statewide Cancer Registry Program); 385.103 (Chronic Disease Community Intervention Program); 381.981 (Health Awareness Campaigns); 381.93 (Mary Brogan Breast and Cervical Cancer Early Detection Program); 381.912 (Cervical Cancer Elimination Task Force); 381.911 (Prostate Cancer Awareness Program); 381.91 (Jessie Trice Cancer Prevention Program); 381.87 (Osteoporosis Prevention and Education Program); 381.04015 (Women's Health Strategy); 381.0032 (Epidemiological Research); 381.0271 (Florida Patient Safety Corporation); 381.0046 (Statewide HIV and AIDS Prevention Program); 430.502 (Alzheimer's Disease Memory Disorder Clinics); and 381.00325, F.S. (Hepatitis Awareness Program).

<sup>13</sup> s. 381.855, F.S.

<sup>14</sup> See also <http://www.ncsl.org/programs/health/genetics/embfet.htm> (viewed April 5, 2007) (containing an in-depth discussion of state embryonic and fetal research laws).

<sup>15</sup> <http://vote2004.ss.ca.gov/voterguide/english.pdf> (viewed April 4, 2007) (presenting the text of the proposition as well as the arguments in favor of, and in opposition to, the proposition).

<sup>16</sup> *Id.* at 147.

<sup>17</sup> See [http://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill\\_num=934&which\\_year=2005&SUBMIT1.x=13&SUBMIT1.y=12&SUBMIT1=Normal](http://www.cga.ct.gov/asp/cgabillstatus/cgabillstatus.asp?selBillType=Bill&bill_num=934&which_year=2005&SUBMIT1.x=13&SUBMIT1.y=12&SUBMIT1=Normal) (viewed April 5, 2007).

<sup>18</sup> *Id.*

<sup>19</sup> <http://www.dph.state.ct.us/StemCell/index.htm> (viewed April 5, 2007).

<sup>20</sup> *Id.*

cell research.<sup>21</sup> Stem cell research includes “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.”<sup>22</sup> Among other restrictions, the executive order prohibited the use of grant funds for research involving reproductive cloning of a human being, fetuses from induced abortions, and the creation of embryos through the combination of gametes solely for the purpose of research.<sup>23</sup> “Cloning of a human being” is defined as “asexual human reproduction by implanting or attempting to implant the product of nuclear transplantation into a woman’s uterus to initiate a human pregnancy.”<sup>24</sup> In 2006, \$10 million in grants were awarded to ten organizations, comprising hospitals and universities.<sup>25</sup>

**Maryland.** In April 2006, Governor Robert Ehrlich signed Senate Bill 144, which created the Maryland Stem Cell Research Fund to promote state-funded stem cell research and cures through grants and loans.<sup>26</sup> “Stem cell” is defined as a human cell that has the ability to (1) divide indefinitely; (2) give rise to many other types of specialized cells; and (3) give rise to new stem cells with identical potential.<sup>27</sup> Up to \$15 million was available for the first round of grants and loans. The bill also revised the then-existing human cloning ban, specifically prohibiting a person conducting state-funded research from engaging in any research that intentionally and directly leads to human cloning.<sup>28</sup> “Human cloning” is defined as the “replication of a human being through the production of a precise genetic copy of nuclear human DNA or any other human molecule, cell, or tissue, in order to create a new human being or to allow development beyond an embryo.”<sup>29</sup>

**New Jersey.** In December 2005, New Jersey awarded \$5 million in grants to 17 organizations to conduct stem cell research, including embryonic research prohibited from receiving federal funding.<sup>30</sup> In 2007, New Jersey will award an additional \$10 million in grants.<sup>31</sup> In addition, in December 2006, Governor Jon Corzine signed Senate Bill 1471, which authorized the New Jersey Economic Development Authority to issue \$270 million in bonds for facilities for stem cell research, biomedical research, blood collection, and cancer research.<sup>32</sup>

### *Human Cloning*

As previously described, somatic cell nuclear transfer (SCNT) may be used to produce embryos to obtain stem cells for scientific research, otherwise known as “therapeutic” cloning. However, SCNT may also be used for reproductive cloning. The most well-known example is that of “Dolly the sheep.” In that example, the embryo that was created from the SCNT process, like therapeutic cloning, carried all of the chromosomes of the donor cell and none of the chromosomes of the host egg cell. The embryo was implanted in a surrogate “mother” and Dolly was subsequently born as an exact genetic copy of her donor mother. However, in early 2003, Dolly died from lung disease most common in older sheep.<sup>33</sup> The necropsy also revealed that Dolly had developed arthritis prematurely.<sup>34</sup>

As of mid-2006, approximately 15 states have banned reproductive cloning, and some additionally ban therapeutic cloning.<sup>35</sup> The federal government does not currently prohibit the practice of human

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<sup>21</sup> <http://www.illinois.gov/Gov/pdfdocs/execorder2005-6.pdf> (viewed April 4, 2007).

<sup>22</sup> *Id.*

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> <http://www.illinois.gov/PressReleases/ShowPressRelease.cfm?SubjectID=1&RecNum=4799> (viewed April 4, 2007).

<sup>26</sup> <http://mlis.state.md.us/2006rs/billfile/sb0144.htm> (viewed April 5, 2007).

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.*

<sup>30</sup> Stem Cell Research in New Jersey (viewed April 4, 2007) <http://www.state.nj.us/scitech/stemcell/>.

<sup>31</sup> *Id.*

<sup>32</sup> [http://www.njleg.state.nj.us/2006/Bills/AL06/102\\_.PDF](http://www.njleg.state.nj.us/2006/Bills/AL06/102_.PDF) (viewed April 4, 2007).

<sup>33</sup> Dolly the sheep dies young (viewed April 6, 2007) <http://www.newscientist.com/article.ns?id=dn3393>.

<sup>34</sup> *Id.*

<sup>35</sup> State Human Cloning Laws (viewed April 6, 2007) <http://www.ncsl.org/programs/health/genetics/rt-shcl.htm>.

cloning. However, the federal Food and Drug Administration (FDA) has explicitly stated that clinical research using cloning technology to create a human is subject to FDA regulation.<sup>36</sup>

### *Ethical Considerations*

Embryonic stem cell research raises a number of ethical issues. On the one hand, the destruction of the embryo is understood by some as the equivalent of the destruction of a human life. On the other hand, some may argue that treatments employing embryonic stem cells may relieve countless individuals from suffering the effects of a number of medical conditions or genetic disorders.

Likewise, reproductive human cloning also raises a number of ethical concerns. These concerns include:

- Early clinical failures may lead to an increase in abortions, birth defects, or early deaths.
- A cloned individual may be prevented from having a unique identity and may experience discrimination.
- Society may, over time, lose respect for the uniqueness of human life through the engineering of individuals without undesirable traits or genetic disorders.
- Cloning may eventually lead to human/animal hybrids.

### Effect of Proposed Changes

The bill creates the Stem Cell Research Advisory Council (“stem cell council”) within the department. The council is composed of the following seven members:

- Secretary of Health, or a designee.
- Two members appointed by the Governor, one of whom must be an academic researcher in the field of stem cell research and one of whom must have a background in bioethics.
- One member appointed by the President of the Senate, who must have a background in private-sector stem cell funding and development or public-sector biomedical research and funding.
- One member appointed by the Speaker of the House of Representatives, who must have a background in private-sector stem cell funding and development or public-sector biomedical research and funding.
- One member appointed by the President of the Senate, who must have a background and experience in either public-sector or private-sector stem cell research and development.
- One member appointed by the Speaker of the House of Representatives, who must be an executive of a biotech company.

Stem cell council members serve two-year terms, with the initial terms staggered. The Secretary of Health acts as chair of the council.

The duties of the stem cell council include:

- Developing a “donated funds program” to encourage development of private-sector funds for human adult stem cell research.
- Identifying specific ways to improve and promote for-profit and not-for-profit human adult stem cell and related research.
- Developing a biomedical research grant program to provide grants to eligible state institutions for human adult stem cell research.

The stem cell council is required to submit an annual progress report on the status of biomedical research to the Florida Center for Universal Research to Eradicate Disease. The report must include, among other items, the amount of grants awarded; the names of the recipients of the grants; the status and progress of stem cell research in the state; and the total amount of biomedical research funding currently flowing into the state. The stem cell council must consult with the Biomedical Ethics Advisory

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<sup>36</sup> 10/26/98 Dear Colleague Letter about Human Cloning (viewed April 6, 2007) <http://www.fda.gov/oc/ohrt/irbs/irbletr.html>.

Council in providing recommendations to the Secretary of Health regarding the award of research grants.

The bill additionally creates the Biomedical Ethics Advisory Council (“ethics council”) within the department. The ethics council is composed of the following seven members:

- The Secretary of Health.
- Two members appointed by the Governor.
- One member appointed by the President of the Senate.
- One member appointed by the Speaker of the House of Representatives.
- One member appointed by the Minority Leader of the Senate.
- One member appointed by the Minority Leader of the House of Representatives.

According to the bill, each member of the ethics council must “demonstrate knowledge and understanding of the ethical, medical, and scientific implications of stem cell research” and must demonstrate knowledge in related fields. Members serve a term of four years, except that the initial terms are staggered.

The ethics council is required to review all stem cell research funded through the Biomedical Research Trust Fund to ensure that research complies with ethical and safety guidelines set forth by the United States Department of Health and Human Services.

The bill requires the Secretary of Health to provide grants from the Biomedical Research Trust Fund based on recommendations from the stem cell council.

The bill restricts the use of funds for research to human adult and amniotic stem cells and prohibits the use of funds for embryonic stem cell research from stem cells obtained through the donor embryo’s death or destruction.

Last, the bill prohibits “human cloning,” providing a second-degree felony for a violation. “Human cloning” is defined as “human asexual reproduction, accomplished by introducing nuclear material from one or more human somatic cells into a fertilized or unfertilized oocyte the nuclear material of which has been removed or inactivated so as to produce a living organism at any stage of development that is genetically virtually identical to an existing or previously existing human organism.”

C. SECTION DIRECTORY:

Section 1. Creates s. 381.99, F.S., relating to the Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act.

Section 2. Amends s. 20.435, F.S., relating to the Biomedical Research Trust Fund.

Section 3. Amends s. 381.86, F.S., relating to the Institutional Review Board within the Department of Health.

Section 4. Provides an effective date of July 1, 2007.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill annually appropriates, beginning in Fiscal Year 2007-2008, \$20 million in recurring general revenue funds, with a 15 percent allowance for administrative costs, over a 10-year period to the Biomedical Research Trust Fund to carry out the purposes of the act.

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

Estimated Expenditures	1st Year	2nd Year
<b>Salaries<sup>a</sup></b>		
1 Program Administrator @ \$55,000	\$75,075	\$77,327
2 Program Assistants @ \$42,000	\$114,660	\$118,100
1 Administrative Assistant @ \$35,000	\$47,775	\$49,208
0.25 Senior Attorney @ \$58,000	\$19,793	\$20,386
0.25 Legal Secretary @ \$35,000	\$11,944	\$12,302
<b>Subtotal</b>	<b>\$269,246</b>	<b>\$277,324</b>
<b>Expense</b>		
1 Professional, w/ maximum travel	\$27,728	\$20,402
2 Professionals, w/ medium travel	\$47,644	\$32,992
1 Support Staff, with no travel	\$12,504	\$6,318
0.25 Professional, w/ limited travel	\$14,216	\$6,890
0.25 Support Staff, w/ no travel	\$12,504	\$6,318
3 Stem Cell Research Advisory Council meetings	\$21,036	\$21,562
2 Stem Cell Research Advisory Council teleconferences	\$1,500	\$1,538
8 Biomedical Ethics Advisory Council meetings	\$56,096	\$57,498
Consultation with National Stem Cell Ethics Experts <sup>b</sup>	\$50,000	\$50,000
Professional development	\$15,000	\$15,375
Program marketing, information dissemination	\$5,000	\$5,125
Annual Report	\$25,000	\$25,625
Honorarium, peer review <sup>c</sup>	\$123,000	\$71,000
Honorarium, quality assurance site visits <sup>d</sup>	\$30,000	\$60,000
Technical services contract <sup>e, f</sup>	\$1,137,423	\$659,725
<b>Subtotal</b>	<b>\$1,578,651</b>	<b>\$1,040,368</b>
<b>Total Estimated Expenditures</b>	<b><u>\$1,847,897</u></b>	<b><u>\$1,317,691</u></b>

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

<sup>b</sup> To develop guidelines and written policies for ethical review of human stem cell research

<sup>c</sup> Based on receiving 150 applications in year one (conducting two funding cycles) and 80 applications in year two.

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

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

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

**1. Revenues:**

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Private sector researchers involved in stem cell research will directly benefit from the availability of grant dollars through this act.

D. FISCAL COMMENTS:

None.

### III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or to take any action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill does not appear to provide sufficient authority to the department, particularly with respect to disbursement of funds for research grants.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Lines 72-87: The council member terms are staggered, but the bill does not specify which members will serve the shorter terms.

Line 109: Eligible institutions are not defined. For the King and Bankhead-Coley Programs, eligible institutions include all universities and research institutions in the state.

Lines 112-113: The department is concerned whether the review of "stem cell research conducted by eligible institutions that receive such grants-in-aid" as recommended by the Stem Cell Research Advisory Council to the Secretary of Health means that the research funded by the program is monitored for progress or if *all* the stem cell research at the institution, whether funded by the program or not, is subject to monitoring.

Lines 114-119: The department recommends a report at the beginning of the calendar year so that the data available to policy makers will not be older than six months by the time the committee meetings held prior to the regular legislative session start.

Lines 146-184: The Biomedical Ethics Advisory Council is created to review research funded through the proposed new program and through the Biomedical Research Trust Fund. The department is concerned that the bill is unclear whether this council is both an institutional review board and an ethics committee. If this council is an institutional review board, the secretary is prohibited from serving as a member. The National Academy of Sciences recommends that institutions engaged in human embryonic stem cell research establish ethics oversight committees, noting that these committees are not replacements for research compliance bodies such as institutional review boards. Note that the recommended oversight is

for embryonic stem cell research in particular not stem cell research in general. Additionally, the National Academy of Sciences recommends that these oversight committees include legal and ethical experts as well as representatives of the public. The department recommends that the council includes a legal member, an ethicist, and a member of the general population.

Lines 165-168: The council member terms are staggered, but the bill does not specify which members will serve the shorter terms.

Lines 281-291: According to the department, based on new federal guidance, the department's IRB no longer reviews human subject research funded through grants-in-aid programs. This policy extends to the proposed stem cell grant program unless otherwise specified in statute. The department recommends revising s. 381.86, F.S. to reflect the change in federal guidance.

#### D. STATEMENT OF THE SPONSOR

No statement submitted.

### **IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES**