The Florida Senate

PROFESSIONAL STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Policy Committee

BILL:	SB 750
INTRODUCER:	Senators Geller, Deutch, and others
SUBJECT:	Stem Cell Research
DATE:	March 26, 2007 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Bedford	Wilson	HP	**Favorable**
2.			CM	
3.			HE	
4.			CJ	
5.			HA	
6.				

I. Summary:

This bill creates the Florida Better Quality of Life and Biomedical Research Act (the act). The bill funds embryonic, amniotic, and adult stem cell research by using $20 million from recurring funds in the General Revenue fund deposited into the Biomedical Research Trust Fund annually, for 10 consecutive years. It specifies that the Department of Health Institutional Review Board (IRB) shall not review research funded through the act. The bill creates the Stem Cell Research Advisory Council (advisory council) to provide programmatic oversight and recommend grant awards. The bill creates the Biomedical Ethics Advisory Council to ensure the adherence to ethical and safety guidelines and procedures. The bill provides duties for both advisory councils. It requires the advisory council to submit an annual report on the state of biomedical research in the state to the Florida Center for Universal Research to Eradicate Disease, the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30.

The bill creates a grants-in-aid program to fund stem cell research. The bill restricts the use of such funds for research on embryonic stem cells to cells taken from donated leftover embryos from in vitro fertilization treatments which would otherwise be thrown away or destroyed. The bill requires the department to develop and maintain on its Internet website a consent form for the donation of embryos for stem cell research. The bill prohibits the purchase or sale of embryonic fetal tissue for research purposes and establishes a criminal penalty. It also prohibits human reproductive cloning and establishes a criminal penalty.

The Department of Health (DOH or department) will be responsible for implementing the grants-in-aid program and supporting the two advisory councils created.

This bill amends ss. 20.435 and 381.86, F.S.

This bill creates s. 381.99, F.S.

II. Present Situation:

Department of Health/Institutional Review Boards/Biomedical Research

Section 381.86, F.S., creates the DOH Institutional Review Board (IRB). This statue requires the DOH to review human subject research in accordance with federal law. This applies only to research under the DOH's jurisdiction, as defined by federal law. The DOH must maintain a "Federalwide Assurance" to receive federal funds for public health research and other public health activities. The Federalwide Assurance is a commitment to the U.S. Department of Health and Human Services, Office of Human Research Protections, that the DOH will review human subject research according to federal regulations.

Human subject research is subject to the IRB review if the DOH is engaged in the research or the research involves the DOH clients, facilities, identifiable data, employees or agents, or federal funds. The DOH IRB is not required when the only involvement of the DOH is funding a grants-in-aid program with non-federal dollars.

Until recently, the DOH IRB reviewed human subject research funded by the James and Esther King Program and the Bankhead-Coley Program. Based on new federal guidance in federal regulations, this is no longer the practice. However, if a grantee's research involves human subjects, then the IRB approval from their university or institution is still required. The research cannot begin without the IRB approval.

The revision to the DOH IRB jurisdiction will apply to a stem cell grants-in-aid program unless otherwise specified in statute. This does not preclude an ethical oversight review. Review by an institutional review board is not the same as a review by an ethical oversight council.

The department currently staffs three other legislatively created research programs with advisory councils. The James and Esther King Biomedical Research Program, the Florida Cancer Center, and the Florida Center for Universal Research to Eradicate Disease (CURED).

Federal Regulation of Stem Cell Research

In November 2001, President George W. Bush created The President's Council on Bioethics "to advise the President on issues that may emerge as a consequence of advances in biomedical science and technology."[1] In particular, the council was authorized to study ethical issues connected with specific technological activities such as embryo and stem cell research. After studying the issue of human cloning, the majority, ten members of the council, voted to ban cloning for the production of children and to place a four-year moratorium on cloning for biomedical research. The minority, seven members, voted to ban cloning for the production of children and to regulate the use of cloned embryos for research.

[1] Executive Order #13237

There are four primary sources for embryonic stem cells: existing stem cell lines, aborted or miscarried embryos, unused in vitro fertilized embryos, and cloned embryos. Current federal policy limits federally funded research to research conducted on embryonic stem cell lines created before August 2001. There are currently more than 60 existing different human embryonic stem cell lines that have been developed from excess embryos created for in vitro fertilization with the consent of the donors and without financial inducement. These existing lines are used in approximately one dozen laboratories around the world (in the United States, Australia, India, Israel, and Sweden). Federal funding of research involving cloning for the purpose of reproduction or research is prohibited. However, there is no federal law banning human cloning altogether. The Food and Drug Administration has claimed authority over the regulation of human cloning technology as an investigational new drug and stated that at this time, they would not approve any projects involving human cloning for safety reasons, but Congress has not passed legislation confirming the FDA's authority to prohibit cloning.[2]

Stem Cell Legislation in Other States

Many state legislatures have been particularly interested in the stem cell debate. In 2005, states considered over 170 bills on embryonic and adult stem cell research. More than a dozen states will carry over legislation, and others will consider new bills. Should embryonic stem cell research be legal? Should state funds support it? Should the state fund adult stem cell research instead? California and New Jersey have taken the lead in supporting stem cell research. Both states have struggled with regulatory issues. California has chosen to create a mini-National Institute of Health (NIH) to oversee research, whereas New Jersey has centralized research.

Stem Cells

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

- 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.
- 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.

There are differences between adult and embryonic stem cells. Adult stem cells are limited in the variety of cells into which they can differentiate and generally only develop into the cell types of the tissue from which they were isolated.[3] Embryonic stem cells are more flexible and can be triggered to produce a range of specialized cells. 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

[2] State Embryonic and Fetal Research Laws, National Conference of State Legislatures, 2005.
[3] Stem Cell Basics. National Institutes of Health. http://stemcells.nih.gov/index.asp. (last visited March 26, 2007).

continues to divide, the cells begin to specialize into particular organ cells. It is for this reason that the most "useful" stem cells are those that have not yet passed the first few divisions.[4] This quality is important because it permits such stem cells to be used to address a variety cures and treatments for disease.

A significant debate about stem cells involves the source of the cells. Human stem cells can be harvested from human embryos (embryonic stem cells) or from the tissue of an adult (adult stem cells). Human embryos are the source for pluripotent stem cells—cells that are capable of giving rise to most tissues of the human organism. The development of embryos for the sole purpose of harvesting the stem cells is considered immoral by many because the embryo is killed. For this same reason, the harvesting of stem cells from any embryo is considered immoral by many.

Reproductive Cloning

Reproductive cloning is the cloning of a human embryo for the purposes of initiating a pregnancy. The debate over reproductive cloning heated up when "Dolly" the sheep was successfully cloned in 1997. Federal funding for cloning research is prohibited and 13 states have passed laws prohibiting reproductive cloning.[5] Several others have banned state funding for reproductive cloning. Florida is one of the many states that have not enacted legislation on the issue.

Ethical Issues

A central ethical issue surrounding embryonic stem cell research involves the status of the human embryo. In general, the stances that people hold on this issue depend on two factors: (1) beliefs on the status of the embryo, and (2) the context in which embryos are acquired and used. In terms of the status of the fetus, stances vary from "embryos are human individuals and should never be used for research," to "embryos are a mere cluster of cells and may be created for the sole purpose of research." The majority of people gravitate to a position between the two stances, holding for example that embryos are "more than just cells," but they do not have the same status as a fetus or baby, and can therefore be used to derive stem cells for research.[6]

In terms of the context in which embryos are acquired, stances also vary. For many people who believe that human life begins at conception, it is wrong to create embryos for the purpose of destroying them; however it is acceptable to use already existing embryos that are left over from in vitro fertilization procedures and would be discarded anyway. This principal is referred to as the "nothing is lost" principle and means if an embryo is not going to be used for its original purpose of reproduction and would be discarded in the future, science should be allowed to make

[4] Hudson, K.L., Scott, J., and Faden, R. 2005. Values in Conflict: Public Attitudes on Embryonic Stem Cell Research. A Report from the Genetics and Public Policy Center. http://www.dnapolicy.org/pub.reports.php. (last visited on March 26, 2007).
[5] National Conference of State Legislatures, State Human Cloning Laws, 2005.
[6] Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. http://www.bioethics.umn.edu/publications/bioethics_overview.html (last visited on March 26, 2007).

use of the embryo prior to its destruction, for research that might benefit people who are alive and suffering from a disability or illness.[7]

Florida Center for Universal Research to Eradicate Disease (CURED)

Florida's Center for Universal Research to Eradicate Disease (CURED) was created by the Florida Legislature in its 2004 Regular Session. Section 381.855, F.S., established the program and created an advisory council to provide policy recommendations to the Legislature. The program is appropriated $250,000 from the annual administrative expenses allocated to the James and Esther King Biomedical Research program.

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.

As part of the enabling legislation for the CURED, the program is charged with holding an annual biomedical technology summit in Florida. 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 Inaugural Summit was successfully held in Palm Beach Gardens in August of 2006, with ninety-five participants that collaborated to define a statewide research agenda. The 2007 Summit is scheduled for August 5-8. The CURED also has not started monitoring the supply and demand of stem cells in Florida and nothing is mentioned in the report about beginning in the immediate future.[8]

Scripps Florida Funding Corporation

Senate Bill 6E, passed during the 2003E legislative session, created s. 288.955, F.S., which creates a not-for-profit organization known as the Scripps Florida Funding Corporation (corporation) for the purpose of receiving, holding, and investing, administering, and disbursing funds appropriated by the Legislature for the establishment and operation of a state-of-the-art biomedical research institution in this state. The funding corporation was responsible for negotiating and executing a contract with the Scripps Research Institute to accomplish this goal. Currently, Florida is moving ahead with the creation of a Scripps Research Institute.

Florida Biomedical Research Program

There are two grant-funding programs within the Florida Biomedical Research Program administered by the DOH Office of Public Health Research. These programs are the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program. An 11-member Biomedical Research Advisory Council (s. 215.5602(3), F.S.) advises the

[7] Hudson, K.L., Scott, J., and Faden, R. 2005. Values in Conflict: Public Attitudes on Embryonic Stem Cell Research. A Report from the Genetics and Public Policy Center. http://www.dnapolicy.org/pub.reports.php (last visited on March 26, 2007).
[8] Annual Report of the Advisory Council of The Florida Center for Universal Research to Eradicate Disease, 2006.

Secretary of Health on the direction and scope of the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program.

In addition to these grant programs, the Office of Public Health Research provides support to the Institutional Review Boards, which protect the health and safety of research participants. Also contained in this office are the Florida Center for Universal Research to Eradicate Disease, which coordinates, improves, expands, and monitors all biomedical research programs within the state, facilitates funding opportunities, and fosters improved technology transfer of research findings into clinical trials and widespread public use, and the Florida Cancer Council, which improves cancer research and treatment to make the state a center of excellence for cancer research.

The James and Esther King Biomedical Research Program

The James and Esther King Biomedical Research Program is created in s. 215.5602, F.S., within the DOH. The purpose of the program is to provide an annual and perpetual source of funding in order to support research initiatives that address the health care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease. The long-term goals of the program are to:

- Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease;
- Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of disease related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease;
- Improve the quality of the state' academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers;
- Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional funding from outside the state; and
- Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

The sum of $6 million is appropriated annually from recurring funds in the General Revenue Fund for the James and Esther King Biomedical Research Program. These funds must be used exclusively for the award of grants and fellowships for research relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.

The Bankhead-Coley Cancer Research Program

On June 13, 2006, Governor Bush signed into law legislation authorizing the investment of $120 million in biomedical research in Florida over a four-year period. The William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (also known as the Bankhead-Coley Cancer Research Program) is an important component of this investment. Beginning in fiscal year 2006-07, the sum of $9 million is appropriated annually from recurring funds in the General

Revenue Fund in response to compelling evidence that more cancer research and improved cancer treatment are necessary in the state.

Codified in s. 381.922, F.S., the program was created effective July 1, 2006, within the DOH, and is supported by the advice and counsel of the Florida Biomedical Research Advisory Council. Section 1 of the enabling legislation for the Bankhead-Coley Cancer Research Program describes three important elements of the legislative intent in creating the program:

- To provide funding to support grants for biomedical research in this state with the anticipation that sustained funding for biomedical research over a period of years will lead to an alleviation of human suffering from diseases such as cancer;
- To dramatically reduce this state's inordinately high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in this state, making this state a world class leader in cancer research and treatment; and
- To stimulate dramatic economic development, particularly in the biotechnology industry, through investment in this state's biomedical research.

Goals for the program include the following:

- Significantly expand cancer research capacity in the state by:
    - Identifying ways to attract new research talent and attendant national grant-producing researchers to cancer research facilities in this state;
    - Implementing a peer-reviewed, competitive process to identify and fund the best proposals to expand cancer research institutes in this state;
    - Funding through available resources for those proposals that demonstrate the greatest opportunity to attract federal research grants and private financial support;
    - Encouraging the employment of bioinformatics in order to create a cancer informatics infrastructure that enhances information and resource exchange and integration through researchers working in diverse disciplines, to facilitate the full spectrum of cancer investigations;
    - Facilitating the technical coordination, business development, and support of intellectual property as it relates to the advancement of cancer research; and
    - Aiding in other multidisciplinary research-support activities as they inure to the advancement of cancer research.
- Improve both research and treatment through greater participation in clinical trials networks by:
    - Identifying ways to increase adult enrollment in cancer clinical trials;
    - Supporting public and private professional education programs designed to increase the awareness and knowledge about cancer clinical trials;
    - Providing tools to cancer patients and community-based oncologists to aid in the identification of cancer clinical trials available in the state; and
    - Creating opportunities for the state's academic cancer centers to collaborate with community-based oncologists in cancer clinical trials networks.

- Reduce the impact of cancer on disparate groups by:
    - Identifying those cancers that disproportionately impact certain demographic groups; and
    - Building collaborations designed to reduce health disparities as they relate to cancer.

Any university or research institute in Florida may apply for grant funding to support these goals, and all qualified investigators in the state, regardless of institution, have equal opportunity to compete for funding. All awards are made based on scientific merit, as determined by open competitive peer review.

III. Effect of Proposed Changes:

Section 1. Amends s. 20.435, F.S., to change the source of funds deposited into and the use of funds in the Biomedical Research Trust Fund. Funds in the trust fund may also be used for the purposes of the Florida Better Quality of Life and Biomedical Research Act created in the bill.

Section 2. Amends s. 381.86, F.S., regarding the Institutional Review Board in the DOH, to specify that the IRB shall review human subjects research except for research involving human embryonic, amniotic, or adult stem cells, and to specify that such research must instead be reviewed by the Stem Cell Research Advisory Council created in the bill.

Section 3. Creates s. 381.99, F.S., entitled the "Florida Better Quality of Life and Biomedical Research Act".

Subsection (1) provides that s. 381.99, F.S., may be cited as the "Florida Better Quality of Life and Biomedical Research Act."

Subsection (2) defines the following terms: adult stem cell, amniotic stem cell, embryonic stem cells, human reproductive cloning, in vitro fertilization, and stem cell.

Subsection (3) establishes the Stem Cell Research Advisory Council (advisory council). The advisory council consists of seven members, including the Secretary of Health and six additional members appointed as follows: two persons appointed by the Governor, one by the President of the Senate, one by the Speaker of the House of Representatives, one by the Minority Leader of the Senate, and one by the Minority Leader of the House of Representatives. The Secretary of Health shall serve as chair of the advisory council. Members shall have specific experience and knowledge in stem cell research, biomedical research, bioethics, and business and financial investments. Members may not serve more than two consecutive two year appointments. Appointments must be made by October 1, 2007, and the first meeting must take place no later than November 1, 2007. The council must meet at least twice per year, but no more than four times in any 12-month period. Members may not be compensated but may be reimbursed for per diem and travel expenses.

This advisory council must work to provide an environment fostering the advancement of embryonic, amniotic, and human adult stem cell research. The advisory council must: develop a recommendation for a donated-funds program; examine and identify specific ways to improve and promote embryonic, amniotic, and human adult stem cell research; develop a recommendation for a grant program to advance embryonic, amniotic, or human adult stem cell research, by December 1, 2007; develop an application for this grant program; after December 1, 2007, receive applications and make recommendations for grant awards; and monitor research institutions receiving grant funding.

The bill requires the advisory council to submit an annual progress report on the state of biomedical research in the state to the Florida Center for Universal Research to Eradicate Disease, the Governor, the Secretary of Health, the President of the Senate, and the Speaker of the House of Representatives by June 30 and specifies the content of the report. It requires council members to disclose any conflict of interest or potential conflict of interest to the Secretary of Health. The bill requires the DOH to provide administrative staff to assist the advisory council in developing a grant application form, reviewing grant applications received, making recommendations to the council, preparing a written consent form, and performing other functions as the council requires.

Subsection (4) creates a seven-member Biomedical Ethics Advisory Council and specifies the membership to include the Secretary of Health as Chair and two persons appointed by the Governor, one by the President of the Senate, one by the Speaker of the House of Representatives, one by the Minority Leader of the Senate, and one by the Minority Leader of the House of Representatives. Members must have specific experience and knowledge in stem cell research and related areas. Members must serve four-year terms but may not serve for more than two consecutive four-year terms. The first meeting must be no later than November 1, 2007. Members must meet at least twice but no more than one meeting per month in any 12-month period. Members may not receive compensation but may receive per diem and travel expense reimbursement.

The bill charges the Biomedical Ethics Advisory Council with the responsibility of reviewing research involving embryonic, amniotic, or human adult stem cells that is funded or supported through the Biomedical Research Trust Fund to ensure adherence to ethical and safety guidelines and procedures of the United States Department of Health and Human Services. Federal regulations (45 CFR 46 and 21 CFR 50 and 56) require review of research involving stem cells. The Biomedical Ethics Advisory Council would be required to review protocols under these regulations and would serve as another IRB from the perspective of federal regulations and the Department's Federalwide Assurance.

Subsection (5) specifies that the Secretary of Health will make grants-in-aid in accordance with the provisions in this section. The bill requires the department to require any applicant for a grant-in-aid to submit an application containing certain information and provides that the advisory council will make recommendations to the Secretary of Health after considering recommendations made by the Biomedical Ethics Advisory Council.

This bill provides that, beginning with the 2007-08 fiscal year, and for 10 consecutive years thereafter, no less than $20 million will be made available from the Biomedical Research Trust

Fund for grants-in-aid for embryonic, amniotic, or human adult stem cell research. Any year end balance not used for grants-in-aid shall be carried forward for the fiscal year next succeeding such grants-in-aid. Up to 15 percent of the funds may be used for administrative costs.

Subsection (6) requires funds provided under this section to be used only for research involving human adult stem cells, human embryonic stem cells taken from donated leftover embryos from in-vitro fertilization treatments which would otherwise be thrown away or destroyed, and amniotic stem cells extracted from human amniotic fluid or placentas. The bill requires a physician or other health care provider who is treating a patient for infertility to give that patient information sufficient to allow the person to make an informed and voluntary choice regarding disposition of any embryos remaining after infertility treatment. It specifies that a person given such information must be presented with the options of storing embryos, donating them to another person, donating them for research purposes, or selecting other means of disposition. If donating for research purposes, the person must give written consent using the form provided by the department and made available to the public on the department's website. It also provides for a second degree felony for certain behaviors relating to buying or selling embryonic fetal tissue for research.

Subsection (7) prohibits human reproductive cloning and makes it a second degree felony to violate this prohibition.

Subsection (8) provides an annual appropriation of $20 million beginning in the 2007-08 fiscal year from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the DOH for the purposes of carrying out this section and ending in the 2016-17 fiscal year. The amount is not to exceed $200 million for the 10 year period.

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

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

There are expenses associated with seeking approval from the Biomedical Ethics Advisory Council for stem cell research funded from the Biomedical Research Trust Fund. To the extent that researchers at private universities and institutions receive research grants there is a positive impact. Depending on the outcome of such research there could be funding from other sources, patents, and licensure/royalty income. To the extent that funded research leads to commercial products, the biotechnology and pharmaceutical industries will benefit, as will residents if jobs are created.

As a result of the funding provided by the proposed program, positive effects are anticipated: increased recognition of Florida as a leader in biomedical research and biotechnology and a favorable location for new or growing business; increased competitiveness for national funding and increased ability to attract top scientists to the state; increased likelihood that treatments and cures are found; and growth of a clean, high-paying employment market.

C. Government Sector Impact:

This bill provides a $20 million appropriation, with a 15 percent allowance for administrative costs, for 10 years. The bill provides no FTEs. The DOH is required to provide support to two advisory councils: the Stem Cell Research Advisory Council and the Biomedical Ethics Advisory Council. Department staff will support the Stem Cell Research Advisory Council in developing a donated funds program (fund raising), identifying specific ways to improve and promote stem cell research and related businesses in the state (scientific capacity and economic development), developing and implementing a stem cell research grants-in-aid program, and producing an annual report. Department staff will also support the Biomedical Ethics Advisory Council in establishing ethical guidelines for human stem cell research and a process for reviewing all research funded by the grants-in-aid program against these guidelines.

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

Estimated Expenditures	1st Year	2nd Year
Salaries[a]		
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
Subtotal	**$269,246**	**$277,324**
Expense		
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[b]	$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[c]	$123,000	$71,000
Honorarium, quality assurance site visits[d]	$30,000	$60,000
Technical services contract[e, f]	$1,137,423	$659,725
Subtotal	**$1,578,651**	**$1,040368**
Total Estimated Expenditures	**$1,847,897**	**$1,317,691**

[a] Salaries are computed w/ 30% fringe, 5% administrative fee, and 3% base salary increase for second year.
[b] To develop guidelines and written policies for ethical review of human stem cell research
[c] Based on receiving 150 applications in year one (conducting two funding cycles) and 80 applications in year two.
[d] Honorarium for quality assurance site visits increases with the number of active grants.
[e] Estimates based on James and 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.
[f] Estimates based on using current contractor. Costs may increase with a different contractor.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill provides for the Secretary of Health to encourage funding from the private sector and recruiting businesses to the state. Such activity could create a conflict of interest for the Secretary in terms of the professions, programs, and entities the Department regulates and oversees.

The provision at page 11, lines 15-18 is vague and offers little guidance as to what standard is to be applied to determine the appropriate status of financial benefit to the state for potential royalties and patents. There could also be a conflict with current law regarding ownership of patents. Sections 286.021 and 286.031, F.S.

This bill amends s. 381.86, F.S., to add a human stem cell IRB that is separate from the existing DOH IRB. Based on new federal guidance, the DOH 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 DOH recommends revising s. 381.86, F.S. to reflect the change in federal guidance.

For staggering council member terms, the bill does not specify which members will serve the shorter terms.

Page 8, line 4, the bill does not require an open, competitive, peer-review process for determining which projects will receive funding. One of the highlights of the King and Bankhead-Coley Programs is the fairness and objectivity of the process. The King Program served as a model when the Legislature created the Bankhead-Coley Cancer Research Program in 2006. Also in 2006, the King Program was the model for changes made to the Johnnie B. Byrd, Sr., Alzheimer's Center and Research Institute at the University of South Florida (s. 1004.445 (8), F.S.). The DOH recommends that the stem cell grant program use the King Program as a model.

Page 8, line 6, eligible institutions are not defined. A definition would help avoid confusion and promote fairness. For the King and Bankhead-Coley Programs, eligible institutions include all universities and research institutions in the state. A statement that both nonprofit and for-profit institutions are eligible would provide additional clarification.

Page 8, line 23, the annual report is due June 30. By requiring a report based on a fiscal year instead of a calendar year, the data available to policy makers will be over six months old by the time the committee meetings held prior to the regular legislative session start. The DOH recommends a due date similar to the Bankhead-Coley, King, and FL CURED Programs.

Page 11, line 15, applicants are asked to propose arrangements concerning financial benefits to the state from patents, royalty payments, or similar gains derived from research that was supported by the stem cell research grant program. If this language is asking applicants to propose sharing in some future gain, then without specific requirements researchers and/or their institutions are unlikely to propose a favorable arrangement. Additionally, depending on the type of research funded (e.g., basic laboratory science or human clinical trials) it may be nearly impossible to link the research funded by the stem cell grants-in-aid program to a specific commercial product or assign a future monetary value.

There is perhaps one example where sharing financial benefits with the state would work – developing stem-cell lines that are then sold to other researchers. The Legislature could request that new stem-cell lines produced with funding from grants provided under s. 381.99, F.S., be given to public institutions or sold to them at a reduced cost. The Legislature might request that institutions return a fixed percentage of all sales made to for-profit organizations. This money could then be used to fund more research grants.

The current DOH standard contract includes the following regarding patents, copyrights, and royalties:

1. If any discovery or invention arises or is developed in the course or as a result of work or services performed under this contract, or in anyway connected herewith, the provider shall refer the discovery or invention to the department to be referred to the Department of State to determine whether patent protection will be sought in the name of the State of Florida. Any and all patent rights accruing under or in connection with the performance of this contract are hereby reserved to the State of Florida.

2. In the event that any books, manuals, films, or other copyrightable materials are produced, the provider shall notify the Department of State. Any and all copyrights accruing under or in connection with the performance under this contract are hereby reserved to the State of Florida.

3. The provider, without exception, shall indemnify and save harmless the State of Florida and its employees from liability of any nature or kind, including cost and expenses for or on account of any copyrighted, patented, or unpatented invention, process, or article manufactured by the provider. The provider has no liability when such claim is solely and exclusively due to the Department of State's alteration of the article. The State of Florida will provide prompt written notification of claim of copyright or patent infringement. Further, if such claim is made or is pending, the provider may, at its option and expense, procure for the Department of State, the right to continue use of, replace, or modify the article to render it non-infringing. If the provider uses any design, device, or materials covered by letters, patent, or copyright, it is mutually agreed and understood without exception that the bid prices shall include all royalties or cost arising from the use of such design, device, or materials in any way involved in the work.

Public universities may be exempt from some of these requirements.

Page 13, line 12, it is not clear if the phrase "human reproductive cloning" includes research and therapeutic cloning or just cloning for the intent of producing a living human clone. A definition would clarify the legislative intent. According to the Congressional Research Service, Report for Congress on Human Cloning from July 20, 2006 (Order Code RL31358), page 11, 15 states have enacted measures to prohibit reproductive cloning, and six states have prohibited cloning for research or therapeutic cloning.

VIII. Summary of Amendments:

None.