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: PCS/SB 2496

INTRODUCER: Health Policy Committee and Senator Haridopolos

SUBJECT: Stem Cell Research

DATE: April 4, 2007 REVISED:

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

I. Summary:

This bill creates the "Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act (the act)." The bill funds the act by appropriating $20 million annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund, for 10 consecutive years, beginning in the 2007-08 fiscal year. The bill creates the Stem Cell Research Advisory Council within the Department of Health (DOH or department) to develop a donated funds program for human adult stem cell research in the state and to recommend a research grant program for adult stem cell research. The bill creates the Biomedical Ethics Advisory Council to review all stem cell research that is funded or supported through the Biomedical Research Trust Fund to ensure that the research follows the ethical and safety guidelines as set forth by federal ethical standards.

The bill creates a grants-in-aid program to fund stem cell research. The bill restricts the use of such funds to human adult stem cells including, but not limited to those derived from umbilical cord blood and bone marrow. Funds may not be used for research with human embryonic stem cells that are derived by a process entailing the donor embryo's death or destruction. The bill specifies that stem cell research will not be reviewed by the Institutional Review Board in the department. The bill requires the department to prepare and distribute a publication regarding the process, options, medical uses, risks, and benefits of umbilical cord blood collection.

The department will be responsible for implementing the grants-in-aid program and supporting the two advisory councils created.

This bill creates s. 381.99, F.S., and one undesignated section of law.

This bill amends ss. 20.435 and 381.86, 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 continues to divide, the cells begin to specialize into particular organ cells. It is for this reason

[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).

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 of 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.

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.[5]

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 use of the embryo prior to its destruction, for research that might benefit people who are alive and suffering from a disability or illness.[6]

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.

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[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] 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).
[6] 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).

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 95 participants who 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.[7]

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 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.

[7] Annual Report of the Advisory Council of The Florida Center for Universal Research to Eradicate Disease, 2006.

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's 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. Creates s. 381.99, F.S., entitled the "Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act."

Subsection (1) provides that s. 381.99, F.S., may be cited as the "Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act."

Subsection (2) defines the following terms: adult stem cell, amniotic stem cell, embryonic stem cell, and stem cell.

Subsection (3) establishes the Stem Cell Research Advisory Council. The advisory council consists of the Secretary of Health or his or her designee and six additional members appointed as follows: two persons appointed by the Governor, two by the President of the Senate, and two by the Speaker 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 per year. Members will serve without compensation but may be reimbursed for per diem and travel expenses.

This advisory council must work to develop a donated funds program other than state appropriations, develop a biomedical research grant program that will provide grants-in-aid, develop an application, review applications, and review the research.

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 time per month during any 12-month

period. Members serve without compensation but may receive per diem and travel expense reimbursement.

The bill charges The Biomedical Ethics Advisory Council with the responsibility of reviewing all stem cell research that is funded or supported through the Biomedical Research Trust Fund to ensure adherence to ethical and safety guidelines of the United States Department of Health and Human Services.

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 Stem Cell Research Advisory Council will make recommendations to the Secretary of Health after considering the recommendations of the Biomedical Ethics Advisory Council.

This bill establishes 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 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 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 including, but not limited to adult stem cells derived from umbilical cord blood and bone marrow. Stem cells may also be derived from post mortem tissues, other than from medically induced abortions. Amniotic stem cells may be used or placentas that are otherwise discarded after birth. Amniotic and adult stem cell material may only be donated for research purposes with the informed consent of the donor. No funds shall be used for research with human embryonic stem cells that are derived by a process entailing the donor embryo's death or destruction.

Subsection (7) provides that, beginning with the 2007-08 fiscal year, the sum of $20 million is appropriated annually from recurring funds in the General Revenue Fund to the Biomedical Research Trust Fund within the DOH. The amount shall not exceed $200 million for the 10-year period beginning in the 2007-08 fiscal year and ending in the 2016-17 fiscal year.

Section 2. 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 must also be used for the purposes of the Florida Hope Offered through Principled, Ethically Sound Stem Cell Research Act created in the bill.

Section 3. 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 that a separate Stem Cell Research Advisory Council and Biomedical Ethics Advisory Council are appointed under s. 381.99, F.S.

Section 4. Requires the department to prepare an educational publication regarding the process, risks, options, medical uses, benefits, and costs of umbilical cord blood collection and donation.

The department is required to distribute the pamphlet free of charge to physicians and health care institutions and make it available on its website in a printable version.

Section 5. 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 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. There may be additional expenses to the department not included here for the pamphlet on umbilical cord blood collection. These figures were not available.

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
.25 Professional, w/ limited travel	14,216	6,890
.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 percent fringe, 5 percent administrative fee, and 3 percent 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 on page 7, lines 17-20, 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, ss. 286.021 and 286.031, F.S.

Given the amendment to s. 381.86, F.S., the roles and duties of the Stem Cell Research Advisory Council and the Biomedical Ethics Advisory Council need to be clarified. It is unclear why the Stem Cell Research Advisory Council is included in the amendment to s. 381.86, F.S. It appears from the proposed language for s. 381.99, F.S., that this council is a programmatic advisory council and not an institutional review board. It is also unclear if the Biomedical Ethics Advisory Council is an institutional review board, an ethics oversight committee, or both. If either advisory council is considered an institutional review board then the Secretary would be prohibited from serving as a member.

Adding the Biomedical Ethics Advisory Council to the statute that creates the DOH IRB suggests that the council is an institutional review board and will review human subject research. This type of review is governed by federal law. However, the description of the council's duties on page 7 suggests that the council is an ethics oversight committee. Ethics reviews are conducted according to agreed upon guidelines. Institutional review boards and ethics oversight committees are distinct bodies formed for two different purposes. Having one council serve as both an IRB and an ethics oversight committee is inconsistent with the distinct purposes of these two types.

On page 3, line 17, for purposes of staggering council member terms, the bill does not specify which members will serve the shorter terms.

On page 4, line 12, 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.

On page 4, line 14, 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.

On page 4, line 23, it is unclear if 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 (as it is in the King and Bankhead-Coley Programs)

On page 4, line 30, 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.

On page 7, lines 17-20, 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.

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.

This Senate Professional Staff Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.

VIII. Summary of Amendments:

None.

This Senate Professional Staff Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.