HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 233 Biomedical Research
SPONSOR(S): Sands and others
TIED BILLS: **IDEN./SIM. BILLS:** SB 468

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee		Bell	Mitchell
2) Criminal Justice Committee			
3) Governmental Operations Committee			
4) Health Care Appropriations Committee			
5) Health & Families Council			

SUMMARY ANALYSIS

HB 233 creates s. 381.99, F.S., to establish the "Florida Better Quality of Life and Biomedical Research Act." The purpose of the Act is to foster medically ethical embryonic and human adult stem cell research in Florida. Currently, the state only supports research on adult stem cells and placenta or cord blood stem cells. The Act provides definitions of related stem cell terms and lists findings to support research in the state.

Developments in the fields of genetics, developmental biology, and information technology are moving stem cell research forward worldwide. Although the research is still in its infancy, experts believe this research could yield promising treatments and cures for certain debilitating diseases and injuries. Stem cell research is not without controversy. Questions persist about the costs and benefits of its use, the possible intended and unintended consequences of the research procedures, and the moral status of early life form from which stem cells are harvested.

To address the ethical issues involved in stem cell research, the bill creates two new councils to oversee stem cell research in Florida. The Biomedical Research Advisory Council is created to promote the advancement of embryonic and human adult stem cell research and the Biomedical Research and Ethics Oversight Council is created as a separate stem cell research institutional review board. The Act allocates $15 million dollars annually for 10 years, out of the existing Biomedical Research Trust Fund to provide for stem cell research.

The bill authorizes the donation of unused embryos from in vitro fertilization that would otherwise be thrown out with the informed consent of the donor.

The bill bans cloning for human reproduction and provides for a second degree felony. It also creates a second degree felony for sale or purchase of embryonic tissue for research purposes related to the Florida Better Quality of Life and Biomedical Research Act.

The estimated fiscal impact of the bill is $15 million dollars annually for 10 years. There is an additional fiscal impact for the Department of Health to implement the provisions of the bill. These costs are estimated at $744,830 in the first year and $593,171 in the second year. The bill sponsor intends to file an amendment to address the Department of Health costs.

The effective date of the bill is July 1, 2006.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides Limited Government – The bill creates two research councils to support adult and embryonic stem cell research in Florida. To accommodate the proposed bill the Department of Health would need to add staff, expand office space, and provide other resources to accommodate three full time employees. The estimated fiscal impact of the bill is $15 million dollars yearly for 10 years. There is an additional fiscal impact for the Department of Health to implement the provisions of the bill. These costs are estimated at $744,830 in the first year and $593,171 in the second year. The bill sponsor intends to file an amendment to address the Department of Health costs.

B. EFFECT OF PROPOSED CHANGES:

HB 233 creates s. 381.99, F.S., to establish the "Florida Better Quality of Life and Biomedical Research Act." The purpose of the Act is to foster embryonic and human adult stem cell research in Florida. Currently, the state only supports research on adult stem cells[1] and placenta or cord blood stem cells. The Act provides definitions of related stem cell terms and lists findings to support research in the state.

The bill creates two new councils to oversee stem cell research in Florida. The Biomedical Research Advisory Council is created to promote the advancement of embryonic and human adult stem cell research and the Biomedical Research and Ethics Oversight Council is created as a separate stem cell research institutional review board. The Act allocates $15 million dollars annually for 10 years, out of the existing Biomedical Research Trust Fund to provide for stem cell research. The bill requires a $15 million dollar appropriation annually for 10 years, from the Legislature.

The bill authorizes the donation of unused embryos from in vitro fertilization[2] that would otherwise be thrown out with the informed consent of the donor.

The bill bans cloning for human reproduction and provides for a second degree felony. It also creates a second degree felony for sale or purchase of embryonic tissue for research purposes related to the Florida Better Quality of Life and Biomedical Research Act.[3]

The effective date of the bill is July 1, 2006.

Biomedical Research Advisory Council

Section 381.99, F.S., creates the Biomedical Research Advisory Council to foster the advancement of embryonic and human adult stem cell research. The Council is charged with overseeing several business, research, and funding aspects of stem cell research in Florida.

This bill provides the Council with certain responsibilities which include:

- developing a recommendation for a private sector donated-funds program to encourage stem cell research in the state;
- examining and identifying specific ways to improve and promote embryonic and human adult stem cell research;
- developing a recommendation for a grant program to advance embryonic or human adult stem cell research; and
- monitoring research institutions receiving grant funding.

[1] Adult stem cells are undifferentiated cells that are found in small numbers in most adult tissues.
[2] In vitro fertilization is provided for in ch. 742, F.S.
[3] Section 873.05, F.S., prohibits the advertising or sale of human embryos in general.

The bill requires the Council to submit an annual progress report on the state of biomedical research 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.

The bill provides detailed requirements of Council members' experience in stem cell research, bioethics, private and public funding, and industry development. The Council will have 7 members with the Secretary of Health acting as chair. The President of the Senate, Speaker of the House of Representatives, Minority Leader of the Senate, and Minority Leader in the House of Representatives will all designate one Council Member. The Governor will appoint two members.

The bill requires the Department of Health (DOH) to provide administrative staff to assist the Council in developing a stem cell research grant application and review of grant applications, developing a written consent form to allow donation of leftover embryos from in vitro fertilization treatments, and to perform other functions as the Council requires.

Biomedical Research and Ethics Oversight Council

The bill creates a Biomedical Research and Ethics Oversight Council to review all embryonic or human stem cell research funded by the Biomedical Research Trust Fund. The Council will ensure adherence to ethical and safety guidelines and procedures established by the United States Department of Health and Human Services. Although the bill does not specifically indicate the Biomedical Research and Ethics Oversight Council as an institutional review board (IRB), per federal regulations[4] it would act as an additional institutional review board (IRB) under the Department of Health (DOH).[5]

The bill amends s. 381.86, F.S., to allow research conducted under the purview of the Biomedical Research and Ethics Oversight Council established by the bill, to be exempt from the existing Department of Health institutional review boards.[6]

The bill specifies that members must have knowledge and understanding of the ethical, medical, and scientific implications of embryonic and adult stem cell research. Members should also be familiar with related biomedical fields. Council members will serve 4 year terms commencing on October 1, 2006. Members may serve two terms. The first meeting of the Council should take place no later than November 1, 2006.

Members are required to meet at least twice annually, but no more than four times a year. The bill provides for members to be reimbursed for per diem and travel expenses. The bill would require DOH to submit a revision of the DOH Federalwide Assurance with the Office of Human Research Protections to add the Biomedical Research and Ethics Oversight Council to the committees of the DOH covered by the Department's Federalwide Assurance. From the perspective of federal regulations, the Biomedical Research and Ethics Oversight Council would serve as a third IRB within the Department of Health.

The proposed bill does not provide for professional and administrative staff support or administrative costs including daily operations, annual report preparation, application in-take or peer review, etc.

[4] Federal regulations 45 C.F.R. 46 and 21 & 21 C.F.R. 50 and 56 require review of research involving stem cells. The Biomedical Research and Ethics Oversight Council would be required to review these protocols.
[5] The Department of Health operates under the Federalwide Assurance within the Office of Human Protections (FWA #00004682).
[6] The Department of Health currently operates IRB #1 & IRB #2 to process the volume of research applications.

Biomedical Research Trust Fund and Grants in Aid

The bill amends s. 20.435, F. S., to authorize the Biomedical Research Trust Fund to provide funding for the proposed, "Florida Better Quality of Life and Biomedical Research Act," s. 381.99, F.S. The Biomedical Research Trust Fund currently is used only for the purposes of the James and Esther King Biomedical Research Program and the Florida Center for Universal Research to Eradicate Disease (CURED).

Section 381.99, F.S., establishes that, beginning with the 2006-07 fiscal year, and for 10 consecutive years thereafter, no less than $15 million each year will be made available from the Biomedical Research Trust Fund for grants-in-aid for embryonic or human adult stem cell research.

The Biomedical Research Trust Fund receives $10.1 million yearly from the Chiles Endowment Fund ($4.1 million) and a distribution of alcoholic beverage tax collections ($6 million).[7] The bill would require an additional $15 million for 10 years to be appropriated from the General Appropriations Act.

The bill requires the Department of Health to require any applicant for a stem cell grant-in-aid to submit an application containing certain information. It provides that the advisory council (not the oversight council) will make recommendations to the Secretary of Health after considering the recommendations of the oversight council. The funding must only be used for embryonic or adult stem cell research. This includes, but is not limited to, adult stem cells derived from umbilical cord blood and bone marrow.

Donation of Unused Embryonic Stem Cell from In Vitro Fertilization

As part of s. 381.99, F.S., the bill authorizes donation of embryonic stem cells taken from donated embryos leftover from in vitro fertilization treatments that would otherwise be thrown away or destroyed. Under the bill a physician or other health care provider is directed to provide information to their patients that allow them to make an informed and voluntary choice about embryo disposition. If the patient decides to donate the unused embryos they must give written consent on a form provided by the Department of Health. The bill provides that embryonic and adult stem cell material may only be donated for research purposes with the informed consent of the donor. The bill creates a second degree felony to knowingly buy, sell, transfer, or obtain embryonic fetal tissue for the research purposes provided in the bill.

The bill also bans human reproductive cloning and creates a second degree felony for the offense.

Definitions

The bill provides a number of definitions relating to stem cell research. Currently, Florida statutes do not define any of the terms defined in HB 233. Section 381.99, F.S., of the bill provides definitions for adult stem cell, asexual reproduction, embryonic stem cells, human reproductive cloning, in vitro fertilization, oocyte, and stem cells.

Legislative Findings

HB 233 creates a rationale statement for supporting stem cell research in Florida. Section 381.99, F.S., provides the following legislative findings:

- An estimated 130 million Americans suffer from acute, chronic, and degenerative diseases and that there is an enormous potential for lifesaving treatment and therapy as a result of recent advances in biomedical research.
- Florida is unique among all states for its large projected net population increase within the next 20 years. This increase, in turn, raises significant health care concerns as a new, larger

[7] ss. 215.5602 and 561.121, F.S. & General Appropriations Act line item 536.

generation of retirees moves to Florida, resulting in a corresponding rise in the number of persons suffering from illnesses such as cancer, heart disease, Alzheimer's Disease, Parkinson's Disease, cerebral palsy, juvenile diabetes, atherosclerosis, amyotrophic lateral sclerosis, AIDS, spinal cord injuries, severe burns, osteoporosis, osteoarthritis, cystic fibrosis, muscular dystrophy, multiple sclerosis, macular degeneration, diabetic retinopathy, retinitis pigmentosa, cirrhosis of the liver, motor neuron disease, brain trauma, stroke, sickle cell anemia, and intestinal diseases.

- In order to maintain a high quality of life for all Floridians, research into stem cell regenerative therapies and treatment should be supported to give hope and relief to the millions of citizens who suffer in silence from degenerative and crippling diseases.
- To reduce the burden on the health care infrastructure, the state must shift its health care objectives from costly long-term maintenance toward prevention and cures.
- To bolster and advance Florida's burgeoning biotechnology industry, the state should provide funds and incentives for private research companies to work in the state.
- The state should advance the goal of scientific and academic discourse in our universities and help bring its public and private universities to the forefront in biomedical research and technology.
- It will benefit the economy of the state to create a wide array of new projects and high-paying jobs related to biomedical research.
- It will benefit the state to foster cooperation between the state's universities and private sector research in terms of jobs, resources, and academic discourse relating to biomedical research.
- The public funds provided under this section are intended to spur innovation and development in Florida's biotechnology sector, which will be used to treat debilitating chronic diseases.

CURRENT SITUATION

Overview

In the 20th century, life spans have increased and human health has improved dramatically in part due to new pharmaceutical drugs and medical treatments based on scientific research. Many of these treatments initially drew public concern, such as early testing and administration of vaccines and the replacement of sulfa drugs with antibiotics.

Currently, proponents of early human stem cell research profess it to be as important as these earlier medical advances. Developments in the fields of genetics, developmental biology, and information technology are moving stem cell research forward worldwide.[8] Although the research is still in its infancy, experts believe this research could yield promising treatments and cures for certain debilitating diseases and injuries.

Stem cell research is not without controversy. Questions persist about the costs and benefits of its use, the possible intended and unintended consequences of the research procedures, and the moral status of early life forms from which stem cells are harvested.[9]

Institutional Review Boards

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

[8] United Kingdom, Belgium, Sweden, Israel, India, Singapore, China, Japan, South Korea and South Africa are some of the world leaders in stem cell research.
[9] Early Stem Cell Research, Center for Practical Bioethics, Spring 2005.

DOH 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 (CURE) all currently operate under the Department of Health. The James and Esther King Biomedical Research program is similar to the proposed Florida Better Quality of Life and Biomedical Research Act.

The James and Esther King Biomedical Research Program

The 1999 Legislature established the Lawton Chiles Endowment Fund (ch. 99-167, L.O.F.), through which the state uses funds received as a result of its settlement with the tobacco industry to enhance or support expansions in children's health care programs, child welfare programs, community-based health and human service initiatives, and biomedical research. Section 215.5602, F.S., establishes the James and Esther King Biomedical Research Program funded from earnings of the endowment fund and provides that funds appropriated to the program are to be devoted to competitive grants and fellowships in research relating to prevention, diagnosis, and treatment of tobacco-related illnesses, including cancer, cardiovascular disease, stroke and pulmonary disease. The research conducted may include stem cell related research.

Federal Regulations

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."[10] 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 4-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.

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.[11] 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 (IND) 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.[12]

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? These are some of the questions lawmakers are asking nationwide in 2006.[13] Both California and New Jersey have taken the lead in supporting stem cell research. Both states have struggled with regulatory issues.

[10] Executive Order #13237.
[11] 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).
[12] State Embryonic and Fetal Research Laws, National Conference of State Legislatures, 2005.
[13] Challenges in 2006, Contemplating Stem Cell Research, National Conference of State Legislature, January, 2006.

California has chosen to create a mini-National Institute of Health (NIH) to oversee research, whereas New Jersey has centralized research.

BACKGROUND

Stem Cells 101

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 that make stem cells unique from other cells:

1. Stem cells can divide thousands of times without error and without breaking down. Scientists can cause one stem cell to produce hundreds of identical stem cells in what is called a line.

2. Stem cells can differentiate into a variety of different cells. Scientists can induce stem cells to become cells with special functions, such as the beating cells of the heart muscle or the insulin-producing cells of the pancreas.[14]

There are differences between adult and embryonic stem cells. Adult stem cells are limited in the variety of cells they can differentiate into and generally only develop into the cell types of the tissue from which they were isolated.[15] 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 that the most "useful" stem cells are those that have not yet passed the first few divisions.[16] 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.

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.[17] Several others have banned state funding for reproductive cloning. Florida is one of the many states that have not weighed in on the issue. The proposed legislation bans reproductive cloning.

Ethical Issues

A central ethical issue surrounding embryonic stem (ES) 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

[14] Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. www.bioethics.umn.edu.
[15] Stem Cell Basics. National Institutes of Health. http://stemcells.nih.gov/index.asp.
[16] 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. www.DNApolicy.org.
[17] National Conference of State Legislatures, State Human Cloning Laws, 2005.

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.[18]

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.[19]

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 the Esther King Biomedical Research program. The fiscal year 2005-2006 budget did not include any full-time staff positions.

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 CURED, the program is charged with holding an annual biomedical technology summit in Florida. 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. However, given its limited budget, CURED has not yet held an annual biotechnology summit. However, one is planned for summer 2006. CURED also has not started monitoring the supply and demand of stem cells in Florida and does not plan to in the immediate future.[20]

Scripps Florida Funding Corporation

SB 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. It is likely the Institute will be built in one of the south Florida communities.

C. SECTION DIRECTORY:

Section 1. Amends s. 20.435, F.S., to expand the use of the Biomedical Research trust fund to include a proposed new statute, s. 381.99, F.S.

[18] Human Stem Cells: An Ethical Overview. Center for Bioethics, University of Minnesota. www.bioethics.umn.edu.
[19] 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. www.DNApolicy.org.
[20] Annual Report of the Advisory Council of The Florida Center for Universal Research to Eradicate Disease, 2005.

Section 2. Amends s. 381.86, F. S., to provide that research involving human embryonic and adult stem cells be reviewed pursuant to the provisions of s. 381.99, F.S., instead of the existing Institutional Review Boards.

Section 3. Creates s. 381.99, F.S., the "Florida Better Quality of Life and Biomedical Research Act," provides definitions, lists legislative findings, creates the biomedical research advisory council, creates the biomedical research and ethics oversight council, provides for a stem cell grant application with the Department of Health, authorizes the donation of unused embryonic stem cells from in vitro fertilization, provides a second degree penalty for the buying or selling of embryonic stem cells, and provides a second degree felony for human reproductive cloning.

Section 4. Provides an effective date of July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Estimated Department of Health Institutional Review Board Revenue

Estimated Revenue	1st Year	2nd Year (Annualized/Recur.)
IRB Revenue		
20 initial reviews****	$30,000	$30,000
10 amendments year one	$5,000	$0
20 amendments year two	$0	$10,000
20 continuing reviews	$0	$10,000
Total Estimated IRB Revenue	**$35,000**	**$50,000**

* FTEs are computed w/ 28% fringe and 3% base salary increase for second year.
** Estimates based on James and Esther King Biomedical Research Program cost. First year is higher for one time only development costs.
*** Mostly additional education for members and office supplies.
**** Estimated based on awarding 20 three-year grants at a total of $750,000 per grant. The number of amendments is a guess.

2. Expenditures:

Estimated Department of Health Expenditures

Estimated Expenditures	1st Year	2nd Year (Annualized/Recur.)
Salaries*		
0.5 Senior Attorney @$50,000	$32,000	$32,960
0.5 Legal Secretary@32,000	$40,960	$42,189
1 Program Administrator @55,000	$70,400	$72,512
0.5 Program Assistant @32,000	$20,480	$21,094
0.5 IRB Admin. Assistant @32,000	$20,480	$21,094
Subtotal	**$184,320**	**$189,850**
Expense		
0.5 FTE Professional, limited travel	$11,060	$5,978

0.5 FTE Support Staff	$8,148	$3,380
1 FTE Professional, maximum travel	$21,393	$10,783
0.5 FTE Professional, limited	$11,060	$5,978
0.5 FTE Support Staff	$8,148	$3,380
Annual Report	$20,000	$20,000
Application & peer review process**	$472,809	$330,700
Program marketing, info. Dissemination	$5,000	$5,000
Travel for two councils	$7,644	$7,873
Additional IRB expense***	$30,250	$30,250
Subtotal	**$595,510**	**$423,322**
Net Expenditures	**$744,830**	**$593,171**

* FTEs are computed w/ 28% fringe and 3% base salary increase for second year.
** Estimates based on James and Esther King Biomedical Research Program cost. First year is higher for one time only development costs.
*** Mostly additional education for members and office supplies.
**** Estimated based on awarding 20 three-year grants at a total of $750,000 per grant. The number of amendments is a guess.

Trust Fund Expenditures

Estimated Expenditures	1st Year	2nd Year (Annualized/Recur.)
	$ 15 million	**$15 million**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

To the extent that researchers at private universities and institutions receive research grants there is a direct positive impact on the private sector. The program may generate monies from patents, and licensure/royalty income depending on the outcome of such research. To the extent that funded research leads to commercial products the biotechnology and pharmaceutical industries will benefit, as will residents if jobs are created. Additionally, the bill may increase the likelihood that treatments and or cures are found for many chronic illnesses.

D. FISCAL COMMENTS:

The proposed bill does not specifically allow or disallow using part of the proposed $15 million for operating costs. A similar program administered by the Department of Health (DOH), the James and Esther King Biomedical Research Program, allows no more than 15% of each year's appropriation for administrative costs.

Although not mentioned in the proposed bill, additional staff and resources will be needed to support the Biomedical Research and Ethics Oversight Council. Unless DOH is allowed to use up to 15 percent of the $15 million for administrative expenses the department would be faced with absorbing the entire cost of providing this support using its allotted general revenue. DOH would need to add staff, expand office space, and provide other resources to accommodate three FTEs, including a 0.5 FTE attorney for the increased legal work associated with the project.

The criminal Justice Impact Conference has not met to consider the prison bed impact of this bill on the Department of Corrections. The two penalties created by the bill may add an additional fiscal impact due to prison costs.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of 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:

No additional rule making authority is required to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Biomedical Research and Ethical Oversight Council

The bill does not make clear that the Biomedical Research and Ethical Oversight Council created in s. 381.99, F.S., is an institutional review board and must comply with federal and state regulations governing research involving humans. The term “institutional review board” is a generic term used to describe the entity in an institution that is responsible for ensuring the health and safety of persons participating in research. It may be called by a different name, but it is still an institutional review board. The lack of clarity in the bill further complicates the ability of the Council to charge for research review. Currently under s. 381.86(5), F.S., the Department of Health (DOH) institutional review board (IRB) may assess fees to support the review of human subject research.

In section s. 215.5602, F.S., there is another body named the Biomedical Research Advisory Council; however, the bill does not amend s. 215.5602, F.S. The bill should provide a unique name for the advisory council it creates to avoid confusion.

Section 381.99, F.S., specifies that the Biomedical Research and Ethical Oversight Council will meet at least twice annually, but no more than four times annually. According to the Department of Health, institutional review boards (IRBs) generally receive application for reviews and amendments on an ongoing basis. Limiting the number of times an IRB committee may meet, would create unnecessary delays in research because the research can not continue until approval is received.

Grant-in-Aid Funding

Previous bills creating a grant program have used the same or similar language as established in, s. 215.5602, F.S., for the James and Esther King Biomedical Research Program. One key component of the grants disseminated for the James and Esther King Biomedical Research Program is an unbiased peer review process. According to the Department of Health, a peer review process is critical to the success of a grant-in-aid program. The grant-in-aid funding program in the Florida Better Quality of Life and Biomedical Research Act does not provide for an unbiased peer review process.

The bill sponsor intends to file amendments to remedy drafting issues.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES