

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: CS/SB 2100

INTRODUCER: Health Regulation Committee and Senator Wise

SUBJECT: Biomedical and Social Research

DATE: March 18, 2010 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	Fav/CS
2.	_____	_____	HE	_____
3.	_____	_____	HA	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE..... Statement of Substantial Changes

B. AMENDMENTS..... Technical amendments were recommended

Amendments were recommended

Significant amendments were recommended

I. Summary:

The committee substitute repeals the Florida Biomedical and Social Research Act, which creates the Review Council for Biomedical and Social Research and subjects any research on human beings conducted under the authority of the Department of Health (DOH) to review and approval by this council. This Act has been replaced by the Institutional Review Board created in the DOH to satisfy federal requirements that an institutional review board review all biomedical and behavioral research on human subjects.¹

The committee substitute also repeals the sections of law that create the Center for Health Technologies, the Cervical Cancer Elimination Task Force and the Florida Cancer Council. The Center for Health Technologies has not been active since 1997. The Task Force was statutorily dissolved on June 30, 2008. The Council met only once and produced only one annual report.

The committee substitute adds the goals to be advanced by the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley Program) when awarding grants for cancer research to the section of law for the Bankhead-Coley Program. Currently these goals

¹ See s. 381.86, F.S.

are located within the provisions of the Florida Cancer Council and are adopted into the Bankhead-Coley Program through a cross-reference.

This bill repeals the following sections of the Florida Statutes: 381.0404, 381.85, 381.912, 381.92, and 381.921.

The bill amends ss. 381.855 and 381.922, F.S.

II. Present Situation:

Florida Biomedical and Social Research Act

Section 381.85, F.S., is the “Florida Biomedical and Social Research Act.”² The purpose of the Act is to provide a procedure by which proposed research on children or adults will be supported with funds appropriated to the DOH and can be efficiently and expeditiously assessed for compliance with the substantive and procedural requirements established by the Review Council for Biomedical And Social Research in rules adopted by the DOH. The Act establishes the Council and requires any research on human beings conducted under the authority of the DOH to be reviewed and approved by the Council.

According to the DOH, the Act does not comply with federal regulations governing the conduct of research involving human subjects and has been replaced by s. 381.86, F.S., which establishes the Institutional Review Board to satisfy federal requirements for human subject research.

Institutional Review Board

In 2004,³ the Legislature enacted s. 381.86, F.S., in order to satisfy federal requirements under 45 C.F.R. part 46 and 21 C.F.R. parts 50 and 56 that an institutional review board review all biomedical and behavioral research on human subjects which is funded or supported in any manner by the DOH. The State Surgeon General determines and appoints the members of the board. The DOH is authorized to adopt any rules necessary to comply with federal requirements. The rules must also prescribe procedures for submitting an application for the Institutional Review Board’s review.

Center for Health Technologies

The Center for Health Technologies was established in 1989⁴ and is required to be located at and administered by a statutory teaching hospital in Miami-Dade County. Its purpose is to encourage the development and growth of health sciences in the state; to assist coordination between and with educational institutions, health care providers, and persons engaged in research and development of health care products; to provide services to persons and incipient firms engaged in the incubation of health care products; to assist in technology transfer; and to establish academic laboratories, libraries, and other resource facilities. It was located at the Mount Sinai Medical Center, but has been inactive since 1997.

² Section 75 of chapter 90-306, Laws of Florida.

³ Section 10 of chapter 2004-350, Laws of Florida.

⁴ Section 10 of chapter 89-354, and Section 13 of chapter 89-527, Laws of Florida.

Cervical Cancer Elimination Task Force

The Cervical Cancer Elimination Task Force was created by the Legislature in 2004.⁵ The purpose of the Task Force was to recommend strategies and actions to reduce the costs and burdens of cervical cancer in Florida. The Task Force was required to submit a final report on June 30, 2008, and was to be dissolved by that date. According to the DOH, the Task Force was never implemented since the funding line item was vetoed and there was no authority to spend general revenue on staff support.

Florida Cancer Council

In 2004, the Legislature established the Florida Cancer Council for the purpose of making the state a center of excellence for cancer research.⁶ Sections 381.92 and 381.921, F.S., specify the membership of the Council and the Council's mission and duties. According to the DOH, the Council was never funded, met only once, and produced only one annual report. The Council's functions were largely taken over by the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program starting in 2006.⁷

III. Effect of Proposed Changes:

Section 1. Repeals s. 381.0404, F.S., which creates the Center for Health Technologies. The Center has been inactive since 1997.

Section 2. Repeals s. 381.85, F.S., which creates the Review Council for Biomedical and Social Research and subjects any research on human beings conducted under the authority of the DOH to review and approval by this council. This section of law has been replaced by s. 381.86, F.S., to satisfy federal requirements that an institutional review board review all biomedical and behavioral research on human subjects which is funded or supported in any manner by the DOH;

Section 3. Amends s. 381.855, F.S., related to the Florida Center for Universal Research to Eradicate Disease, to delete the Florida Cancer Council from the list of entities that must be represented on the Center's advisory council. Section 5 of the committee substitute repeals the statutory authority for the Florida Cancer Council.

Section 4. Repeals s. 381.912, F.S., which creates the Cervical Cancer Elimination Task Force. The Task Force was statutorily dissolved on June 30, 2008.

Section 5. Repeals s. 381.92, F.S., which creates the Florida Cancer Council. This Council was never funded and has been inactive.

Section 6. Repeals s. 381.921, F.S., which establishes the mission and duties of the Florida Cancer Council. Section 5 of the committee substitute repeals the statutory authority for the Florida Cancer Council.

Section 7. Amends s. 381.922, related to the William G. "Bill" Bankhead, Jr., and David Coley Cancer Research Program, to add the current goals of the program that are to be advanced when

⁵ Section 15 of chapter 2004-2, Laws of Florida.

⁶ Sections 10 and 11 of chapter 2004-2, Laws of Florida.

⁷ See s. 381.922, F.S.

providing grants for cancer research. These goals are enumerated in s. 381.921, F.S., which is repealed in section 6 of this bill.

Section 8. Provides an effective date of July 1, 2010.

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 Art. I, s. 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. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

- A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Regulation on March 18, 2010:

Repeals s. 381.0404, F.S., related to the Center for Health Technologies and amends the current goals for awarding grants under the Bankhead-Coley Program into that program's authorizing statute.

- B. **Amendments:**

None.

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