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 Committee on Education Postsecondary

BILL:	CS/SB 1356
INTRODUCER:	Education Postsecondary Committee and Senator Burton
SUBJECT:	Florida Institute for Pediatric Rare Diseases
DATE:	March 19, 2025 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Jahnke	Bouck	HE	**Fav/CS**
2.			AHS	
3.			FP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 1356 codifies the Florida Institute for Pediatric Rare Diseases (Institute) within the Florida State University College of Medicine as a statewide resource dedicated to research and clinical care related to pediatric rare diseases. The Institute will conduct research, develop diagnostic and genetic screening tools, provide multidisciplinary clinical services and care, educate and train healthcare professionals, and collaborate with other institutions and organizations.

The bill requires the Institute to establish and administer the Sunshine Genetics Pilot Program for five years. This opt-in pilot program offers genetic screening, to include whole genome sequencing to newborns, contingent upon parental consent. Clinical findings from the screening must be released to the newborn's healthcare practitioner and parent. The Institute is required to maintain a secure database of pilot program data and provide deidentified data to support research.

Additionally, the bill establishes the Sunshine Genetics Consortium (Consortium) to facilitate collaboration among researchers, geneticists, and physicians from Florida's state universities and children's hospitals. The Consortium's responsibilities include integrating genomic sequencing technologies, advancing genetic and precision medicine research, educating healthcare professionals, leveraging artificial intelligence in genomics, and securing external funding to expand genetic screening efforts. An oversight board appointed by state universities and government officials will administer the Consortium and meet at least once every six months.

The bill appropriates $5 million in recurring funds from the General Revenue Fund for Fiscal Year 2025-2026 to support the Institute, with an additional appropriation of $20 million in nonrecurring funds specifically designated for the implementation of the Sunshine Genetics Pilot Program.

The bill takes effect July 1, 2025.

II. Present Situation:

Rare Diseases

In the United States, a rare disease is any condition that nationally affects fewer than 200,000 people. There may be as many as 10,000 rare diseases impacting the lives of 30 million Americans and their families.[1] So, while the individual diseases may be rare, the total number of people impacted by a rare disease is large. Rare diseases include genetic disorders, infectious diseases, cancers, and various other pediatric and adult conditions. A rare disease can affect anyone at any point in their life and can be acute or chronic. It is estimated that 80 percent or more of rare diseases are genetic. For rare genetic diseases, genetic testing is often the only way to make a definitive diagnosis.[2]

Rare diseases present a fundamentally different array of challenges compared to those of more common diseases; often, patients are set on a "diagnostic odyssey" in order to determine the cause of their symptoms as they seek treatment in healthcare settings where their condition may have never been seen before.[3]

The Andrew John Anderson Pediatric Rare Disease Grant Program

In 2024, the Florida Legislature established the Andrew John Anderson Pediatric Rare Disease Grant Program (Grant Program) within the Department of Health (DOH) to support research on pediatric rare diseases. The Grant Program awards grants through a competitive, peer-reviewed process to advance new diagnostics, treatments, and cures.[4]

The DOH, in consultation with the Rare Diseases Advisory Council,[5] awards grants to universities and established research institutes in Florida for scientific and clinical research. Preference may be given to proposals that foster collaborations among institutions, researchers, and community practitioners.[6]

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[1] National Organization for Rare Diseases (NORD), *NORD Rare Disease Database*, https://rarediseases.org/rare-diseases/ (last visited Mar. 10, 2025).
[2] Department of Health, *Rare Disease Advisory Council: Legislative Report, Fiscal Year 2023-2024* (2024), at 6-7, *available at* https://www.floridahealth.gov/provider-and-partner-resources/rdac/_documents/2024-rdac-annual-report.pdf.
[3] *Id.*
[4] Section 381.991(1)(a), F.S.; *See also* ch. 224-246, Laws of Fla.
[5] *See* Section 381.99, F.S. The Rare Disease Advisory Council is created adjunct to the DOH for the purpose of providing recommendations on ways to improve health outcomes for individuals residing in this state who have a rare disease.
[6] Section 381.991(1)(b) – (2)(a), F.S. *See also*, Florida Health, *Rare Pediatric Diseases Research Grant Program*, https://www.floridahealth.gov/provider-and-partner-resources/research/research-programs1/RarePediatricDiseasesResearchGrantProgram.html (last visited Mar. 10, 2025).

In both 2023 and 2024, the Legislature appropriated $500,000 for the Grant Program.[7]

Florida State University Institute for Pediatric Rare Diseases

In 2024, Florida State University (FSU) established the Institute for Pediatric Rare Diseases (Institute) at the FSU College of Medicine. It is the mission of the Institute to transform the lives of children affected by rare diseases through research, education, diagnosis, and clinical care.[8]

The goals include:[9]

- Harnessing interdisciplinary collaboration by bringing together scientists, clinicians, and educators to address the challenges of pediatric rare diseases.
- Leveraging advancements in gene therapy and immune response research to improve treatment outcomes.
- Enhancing the quality of life for the 15 million children across the United States affected by pediatric rare diseases.

In 2023, the Legislature allocated $1,000,000 to the Institute,[10] and another $5,000,000 in 2024.[11]

Newborn Screening Program

The Legislature created the Florida Newborn Screening Program (NSP) within the DOH, to promote the screening of all newborns for metabolic, hereditary, and congenital disorders known to result in significant impairment of health or intellect.[12] The NSP also promotes the identification and screening of all newborns in the state and their families for environmental risk factors such as low income, poor education, maternal and family stress, emotional instability, substance abuse, and other high-risk conditions associated with increased risk of infant mortality and morbidity to provide early intervention, remediation, and prevention services.[13]

The NSP attempts to screen all newborns for hearing impairment and to identify, diagnose, and manage newborns at risk for select disorders that, without detection and treatment, can lead to permanent developmental and physical damage or death.[14] The NSP is intended to screen all

[7] Specific Appropriation 539A, s. 3, ch. 2023-239, Laws of Fla., and Specific Appropriation 546A, s. 3, ch. 2024-231, Laws of Fla.
[8] Florida State University, Florida State University News, *FSU launches groundbreaking Institute for Pediatric Rare Diseases*, https://news.fsu.edu/news/health-medicine/2024/02/01/fsu-launches-groundbreaking-institute-for-pediatric-rare-diseases/; *See also*, Florida State University, *Institute for Pediatric Rare Diseases*, https://med.fsu.edu/iprd/home (last visited Mar. 10, 2025).
[9] *Id.*
[10] Specific Appropriation 143, s. 2, ch. 2023-239, L.O.F.
[11] Specific Appropriation 147, s. 2, ch. 2024-231, L.O.F.
[12] Section 383.14(1), F.S.
[13] Section 383.148(1), F.S
[14] Florida Department of Health, *Florida Newborn Screening 2022 Guidelines, available at* https://floridanewbornscreening.com/wp-content/uploads/NBS-Protocols-2022-FINAL.pdf. *See also*, Florida Newborn Screening, https://floridanewbornscreening.com/ (last visited Mar. 10, 2025)

prenatal women and newborns, however, parents and guardians may choose to decline the screening.[15]

Newborn screenings are completed after the baby is 24 hours of age and before discharge from the hospital. For births outside a hospital setting, the birth provider either completes the screening or arranges for testing within 1- 2 days after birth.[16]

The Florida Genetics and Newborn Screening Advisory Council advises the DOH on disorders to be included in the NSP panel of screened disorders and the procedures for collecting and transmitting specimens.[17] Florida's NSP currently screens for 58 conditions, 55 of which are screened through the collection of blood spots.[18] Healthcare providers collect drops of blood from the newborn's heel on a standardized specimen collection card which is then sent to the state laboratory for testing.[19]

If necessary, healthcare providers refer patients to the appropriate health, education, and social services.[20] Screening results are released to the newborn's healthcare provider; in the event of an abnormal result, the baby's healthcare provider or a nurse or specialist from NSP's Follow-up Program provides follow-up services and referrals for the child and his or her family.[21]

III. Effect of Proposed Changes:

CS/SB 1356 creates s. 1004.4210, F.S., to codify the Florida Institute for Pediatric Rare Diseases (Institute) within the Florida State University College of Medicine as a statewide resource for pediatric rare disease research and clinical care. The Institute's purpose is to enhance the quality of life and health outcomes for children and families affected by rare diseases by advancing knowledge, diagnosis, and treatment of pediatric rare diseases through research, clinical care, education, and advocacy. The bill specifies the goals of the Institute, which are:

- Conducting research to better understand the causes, mechanisms, and potential treatments for pediatric rare diseases, including leveraging emerging research methods
- Developing advanced diagnostic and genetic screening tools and techniques to enable healthcare providers to identify rare diseases in newborns and children more rapidly, accurately, and economically.
- Providing comprehensive, multidisciplinary clinical services and care for affected children and their families. Such care may include, but is not limited to, patient, family, and caregiver

[15] Section 383.14(4), F.S.; Rule 64C-7.008, F.A.C.; The hospital provider shall request any parent or guardian who objects to infant (postnatal) risk screening of their child or ward, after the purpose of the screening has been fully explained, to indicate the objection in writing on the electronic birth record risk screening instrument.
[16] Florida Newborn Screening, *What is Newborn Screening?*, https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited Mar. 10, 2025).
[17] Section 383.14(6)(a), F.S.
[18] Department of Health, *2024 Agency Analysis of HB 1441* (Feb. 5, 2024).
[19] Florida Newborn Screening Program, *What is Newborn Screening? available at* https://floridanewbornscreening.com/parents/what-is-newborn-screening/ (last visited March 10, 2025). *See also*, Florida Newborn Screening, Specimen Collection Card, http://floridanewbornscreening.com/wp-content/uploads/Order-Form.png (last visited March 10, 2025).
[20] *Id.*
[21] Department of Health, *2024 Agency Analysis of HB 1441* (Feb. 5, 2024).

support and resources to help navigate the challenges associated with these conditions, support groups, and patient advocacy.
- Educating and training healthcare professionals, including, but not limited to, genetic counselors, pediatricians, scientists, and other specialists.
- Establishing collaborations with other research institutions, medical centers, patient and family advocacy organizations, and government agencies.

The bill requires the Institute to establish and administer the Sunshine Genetics Pilot Program for five years, providing genetic screening, including, but not limited to, whole genome sequencing to newborns in addition to the state's existing newborn screening program. Upon approval of the oversight board, the genetic screening will be performed by the Institute and institutional members of the oversight board. The Institute is authorized to partner with Florida universities and colleges and healthcare service providers to promote and assist in the implementation of the pilot program. Parental consent is required for participation and the Institute and institutional members of the oversight board must release clinical findings of a newborn's screening to the newborn's health care practioner and the newborn's parent.

The bill defines "health care practitioner" to include:
- a physician or physician assistant licensed under chapter 458;
- an osteopathic physician or physician assistant licensed under chapter 459;
- an advanced practice registered nurse, registered nurse, or licensed practical nurse licensed under part I of chapter 464;
- a midwife licensed under chapter 467;
- a speech-language pathologist or audiologist licensed under part I of chapter 468;
- a dietitian or nutritionist licensed under part X of chapter 468; or
- a genetic counselor licensed under part III of chapter 483.

The bill requires the Institute to:
- Maintain a secure database to collect and store all pilot program data, including, but not limited to, newborn genomics sequence data and deidentified new born data.
- Provide deidentified newborn data to members of the Consortium pursuant to a data sharing agreement to support ongoing and future research.

Additionally, by December 1, 2030, the Institute is required to provide a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on the pilot program, including, at a minimum:
- Study population and enrollment metrics.
- Whole genome sequencing metrics.
- Clinical and public health impact.
- Cost effectiveness and economic benefits.

The bill also establishes the Sunshine Genetics Consortium (Consortium) to create a network of clinical and academic research professionals, geneticists, and physicians from state universities and the state's children's hospitals to collaborate with leaders in the genetic industry, build, and support a culture of collaborative research and the development of cutting-edge genetic and precision medicine in the state. The Consortium will:

- Integrate state-of-the-art genomic sequencing technologies.
- Advance research and the development of cutting-edge genetic and precision medicine.
- Leverage artificial intelligence in genomics.
- Develop clinician education on genomic tools.
- Support education and growth of geneticists to meet demand.
- Solicit and leverage external funding to expand the pilot program and support genetic screenings by institutional members of the oversight board.
- Promote patient care to support families with children diagnosed with genetic disorders.
- Report on the use of deidentified newborn data by members of the Consortium.

The bill requires the Consortium to be administrated at the Institute by an oversight board and meet at least once every six months. The oversight board consist of the director of the Institute, who serves as chair, and the following voting members who are required to serve two-year terms:

- One member nominated by the dean of the University of Florida's College of Medicine and approved by the university's president.
- One member nominated by the dean of the University of South Florida's College of Medicine and approved by the university's president.
- One member nominated by the dean of the University of Miami's School of Medicine and approved by the university's president.
- One member appointed by the Governor.
- One member appointed by the President of the Senate.
- One member appointed by the Speaker of the House of Representatives.

The oversight board is responsible for the promotion and oversight of the Consortium, including, but not limited to, the nomination and appointment of members of the Consortium.

The bill requires the Consortium, beginning October 15, 2026, and annually thereafter, to provide a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives on research projects, research findings, community outreach initiatives, and future plans for the Consortium.

The bill appropriates $5 million in recurring funds from the General Revenue Fund for Fiscal Year 2025-2026 to support the Institute, with an additional appropriation of $20 million in nonrecurring funds specifically designated for the implementation of the Sunshine Genetics Pilot Program.

The bill takes effect July 1, 2025.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

D. State Tax or Fee Increases:

None.

E. Other Constitutional Issues:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

The bill appropriates $5 million in recurring funds from the General Revenue Fund for Fiscal Year 2025-2026 to support the Institute, with an additional appropriation of $20 million in nonrecurring funds specifically designated for the implementation of the Sunshine Genetics Pilot Program..

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill creates section 1004.4210 of the Florida Statutes.

IX. Additional Information:

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

CS by Education Postsecondary on March 17, 2025:
The committee substitute maintains provisions in SB 1356, with the following modifications:

- Removes the requirement for the Consortium to create a biorepository network.
- Removes the requirement for the pilot program to be implemented in accordance with specific genetic testing regulations.
- Extends the duration of the Sunshine Genetics Pilot Program from three years to five years.
- Clarifies genetic testing as whole genome sequencing.
- Specifies that the Institute and institutional members of the oversight board, upon approval, will perform the genetic screening.
- Authorizes, rather than requires, the Institute to establish partnerships to promote and assist in the implementation of the pilot program.
- Clarifies that clinical findings of a newborn's screenings must be delivered to both the newborn's healthcare practitioner and parent.
- Specifies that the Institute must collect and store pilot program data, explicitly including genomics sequence data and deidentified newborn data.
- Requires the Institute to provide deidentified newborn data to members of the Consortium pursuant to a data sharing agreement to support ongoing and future research.
- Revises the Institute's reporting requirements on the pilot program specifying that, by December 1, 2030, the Institute must provide a report to include an overview of key metrics and the program's impact on health, cost-effectiveness, and economic benefits.
- Requires the Consortium to advance research and the development of cutting edge genetic and precision medicine.
- Clarifies that the Consortium must solicit and leverage funds, rather than simply raise them, and expands the purpose of funding to explicitly support genetic screenings by institutional members of the oversight board in addition to expanding the pilot program.
- Requires the Consortium to report on the use of deidentified newborn data by members of the Consortium.
- Specifies that the Consortium's oversight board must meet at least every six months.
- Requires the director of the Institute to serve as the chair of the oversight board.
- Modifies the selection process for university-approved members of the Consortium oversight board.
- Revises the oversight board's responsibilities from financial and technical management to general promotion and oversight of the Consortium.
- Specifies that the Consortium's annual reporting must begin on October 15, 2026, and expands reporting requirements to include research projects, findings, community outreach initiatives, and future plans.

- Broadens the scope of the $20 million appropriation from funding only whole genome sequencing at birthing centers to supporting the full implementation of the Sunshine Genetics Pilot Program.

B. Amendments:

None.