A bill to be entitled

An act relating to the Florida Institute for Pediatric Rare Diseases; creating s. 1004.4211, F.S.; establishing the Florida Institute for Pediatric Rare Diseases within the Florida State University College of Medicine; providing the goals of the institute; requiring the institute to establish and administer the Sunshine Genetics Pilot Program for a specified period; providing the purpose of the pilot program; providing institute responsibilities and duties relating to the pilot program; providing requirements for participation in the pilot program and data collection and release in the pilot program; defining the term "health care practitioner"; providing reporting requirements for the pilot program; establishing the Sunshine Genetics Consortium for specified purposes; requiring the consortium to be administered at the institute by an oversight board; providing for the membership and terms of the board; providing meeting and reporting requirements for the consortium; providing that specified provisions will be implemented subject to available funding in the General Appropriations Act; providing an effective date.

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 1004.4211, Florida Statutes, is created to read:

1004.4211 The Florida Institute for Pediatric Rare Diseases; the Sunshine Genetics Pilot Program; the Sunshine Genetics Consortium.—

(1) The Florida Institute for Pediatric Rare Diseases is established within the Florida State University College of Medicine as a statewide resource for pediatric rare disease research and clinical care. The purpose of the institute is to improve 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.

(2) The goals of the institute are to:

(a) Conduct research to better understand the causes, mechanisms, and potential treatments for pediatric rare diseases, including leveraging emerging research methods.

(b) Develop advanced diagnostic and genetic screening tools and techniques to enable health care providers to identify rare diseases in newborns and children more rapidly, accurately, and economically.

(c) Provide comprehensive multidisciplinary clinical services and care for children with rare diseases. Such care may include, but is not limited to, patient, family, and caregiver support and resources to help navigate the challenges associated with these conditions, support groups, and patient advocacy.

(d) Educate and train health care professionals, including, but not limited to, genetic counselors, pediatricians, scientists, and other specialists in the field of pediatric rare diseases.

(e) Establish collaborations with other research institutions, medical centers, patient and family advocacy organizations, and government agencies whenever deemed appropriate by the institute director to share expertise, raise awareness, and promote a collective effort to tackle pediatric rare diseases.

(3)(a) The institute shall establish and administer the Sunshine Genetics Pilot Program to be administered for a period of 5 years. The pilot program shall provide newborn genetic screening, including, but not limited to, whole genome sequencing. Genetic screening shall be performed by the institute and institutional members of the oversight board upon approval of the oversight board.

(b) The institute may establish partnerships with Florida universities and colleges and health care service providers to promote and assist in the implementation of the pilot program.

(c) The pilot program shall be an opt-in program and a parent of a newborn must provide consent to participate in the

<u>pilot program.</u>

<u>(d) The institute and institutional members of the oversight board shall release clinical findings of a newborn's screening to the newborn's health care practitioner and the newborn's parent. As used in this paragraph, the term "health care practitioner" means 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.</u>

<u>(e) The institute shall:</u>

<u>1. Maintain a secure database to collect and store all pilot program data, including, but not limited to, newborn genomics sequence data and deidentified newborn data.</u>

<u>2. Provide deidentified newborn data to members of the consortium pursuant to a data sharing agreement to support ongoing and future research.</u>

<u>(f) By December 1, 2030, the institute shall provide a report on the Sunshine Genetics Pilot Program to the Governor, the President of the Senate, and the Speaker of the House of Representatives. The report must include, at a minimum:</u>

1. Study population and enrollment metrics.

2. Whole genome sequencing metrics.

3. Clinical and public health impact.

4. Cost effectiveness and economic benefits.

(4)(a) The Sunshine Genetics Consortium is established 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 and build and support a culture of collaborative research and the development of cutting edge genetic and precision medicine in the state. The consortium shall:

1. Integrate state-of-the-art genomic sequencing technologies.

2. Advance research and the development of cutting edge genetic and precision medicine.

3. Leverage advancements in artificial intelligence utilization in genomics.

4. Develop educational opportunities for clinicians on genomic tools.

5. Support the growth and education of geneticists to meet demand.

6. Solicit and leverage funds from nonprofits, private industry, and others for the purpose of expanding the Sunshine Genetics Pilot Program and to support genetic screenings by

institutional members of the oversight board.

7. Promote patient care that supports families with children diagnosed with genetic disorders.

8. Report on the use of deidentified newborn data by members of the consortium.

(b)1. The consortium shall be administered at the institute by an oversight board. The board shall convene at least once every 6 months.

2. The oversight board for the consortium shall consist of the director of the institute who shall serve as chair and the following voting members who shall serve 2-year terms:

a. One member nominated by the dean of the University of Florida's College of Medicine and approved by the university's president.

b. One member nominated by the dean of the University of South Florida's College of Medicine and approved by the university's president.

c. One member nominated by the dean of the University of Miami's School of Medicine and approved by the university's president.

d. One member nominated by the dean of Florida International University's College of Medicine and approved by the university's president.

e. One member nominated by Nicklaus Children's Hospital and approved by the hospital's president and chief executive officer.

f. One member appointed by the Governor.

g. One member appointed by the President of the Senate.

h. One member appointed by the Speaker of the House of Representatives.

3. The board shall be responsible for the promotion and oversight of the consortium, including, but not limited to, the nomination and appointment of members of the consortium.

(c) Beginning October 15, 2026, and annually thereafter, the consortium shall 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.

(5) The provisions of this section shall be implemented to the extent of available appropriations contained in the annual General Appropriations Act for such purpose.

Section 2. This act shall take effect July 1, 2025.