Tab 1	**SB 312** by **Rodriguez;** Identical to H 00369 Patient-directed Medical Orders

The Florida Senate

COMMITTEE MEETING EXPANDED AGENDA

HEALTH POLICY
Senator Burton, Chair
Senator Harrell, Vice Chair

MEETING DATE: Tuesday, December 9, 2025
TIME: 10:00 a.m.—12:00 noon
PLACE: *Pat Thomas Committee Room,* 412 Knott Building

MEMBERS: Senator Burton, Chair; Senator Harrell, Vice Chair; Senators Berman, Calatayud, Davis, Gaetz, Leek, Osgood, Passidomo, and Trumbull

TAB	BILL NO. and INTRODUCER	BILL DESCRIPTION and SENATE COMMITTEE ACTIONS	COMMITTEE ACTION
1	**SB 312** Rodriguez (Identical H 369)	Patient-directed Medical Orders; Revising definitions and defining the term "patient-directed medical order"; authorizing the execution of a patient-directed medical order for a specified purpose; requiring that certain health care services be provided to the principal regardless of the decision to withhold or withdraw life-prolonging procedures; authorizing physicians, physician assistants, and advanced practice registered nurses to withhold or withdraw life-prolonging procedures under certain circumstances without penalty; requiring the Agency for Health Care Administration to create and update a database for the storage of patient-directed medical orders, etc. HP 12/09/2025 Favorable AHS FP	Favorable Yeas 7 Nays 0
2	Presentation on the Cancer Connect Collaborative's Annual Report on the Cancer Innovation Fund – Department of Health		Presented
	Other Related Meeting Documents		

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 Health Policy

BILL:	SB 312
INTRODUCER:	Senator Rodriguez
SUBJECT:	Patient-directed Medical Orders
DATE:	December 8, 2025
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rainer	Brown	HP	**Favorable**
2.			AHS	
3.			FP	

I. Summary:

SB 312 creates a new type of advance directive called a "patient-directed medical order" (PDMO), which is a medical order developed between patient and a physician, a physician assistant, or autonomous[1] advanced practice registered nurse. The document is a medical order which deals with the immediate anticipated issues of end-of-life care. The bill harmonizes and coordinates this new advance directive order within the existing panoply of advance directives and other end-of-life legal instruments: living will, designation of health care surrogate, durable power of attorney, anatomical gifts, and do-not-resuscitate order (DNRO).

The bill provides an effective date of July 1, 2026.

II. Present Situation:

Advance Directives

Advance directives are legal instruments that are witnessed and can be either written or an oral statement. The purpose of an advance directive is to provide patients' desires concerning any aspect of their health care in the event they are incapacitated or incompetent, thereby providing real-time informed consent to medical treatment or protocols.[2] An advance directive may also

[1] An autonomous advanced practice registered nurse is licensed under ch. 464, F.S., and registered to practice primary care autonomously under s. 464.0123, F.S.

[2] Sections 765.101(1) and (10) ,and 765.102(2), F.S.

designate a person who can make health care decisions[3] or receive health care information[4] for the patient immediately or when the patient is incapacitated or incompetent.[5]

To validly create an advance directive, the patient must be competent.[6] A patient is deemed as having "incapacity" or being "incompetent" if he or she is "physically or mentally unable to communicate a willful and knowing health care decision."[7] The authorizations under ch. 765, F.S., which allow the withholding or withdrawing of life-prolonging procedures "do not apply to a person who never had capacity to designate a health care surrogate or execute a living will."[8]

To validly form a written advance directive, it must be signed by the patient in the presence of two subscribing adult witnesses.[9] For a living will, designation of health care surrogate, and anatomical gifts, one of the witnesses cannot be a spouse or blood relative of the patient.[10] For a designation of health care surrogate, neither witness may be the designated surrogate or alternate.[11] The patient's signature may be made to a living will or designation of health care surrogate by oral direction of the patient if they are physically unable to do so. One of the witnesses signs the patient name to the living will or designation of health care surrogate in the patient's presence and at the patient's direction.[12] For the designation of a health care surrogate for a minor, an advance directive must be signed by the natural guardian, legal custodian, or legal guardian, and can provide for a signature of such guardian in absentia if such guardian provides such instruction in the presence of the witnesses.[13]

Oral advance directives are generically recognized.[14] However, there is no specific statute which distinctly describes the requirements for an oral advance directive to be valid. Oral (as well as

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[3] Section 765.101(6), F.S. "health care decision" is defined as:
(a) informed consent, refusal of consent, or withdrawal of consent to any and all health care, including life-prolonging procedures;
(b) the decision to apply for private, public, government, or veterans' benefits to defray the cost of health care;
(c) the right of access to health information of the principal reasonably necessary for a health care surrogate or proxy to make decisions involving health care and to apply for benefits; and
(d) the decision to make an anatomical gift pursuant to part V of this Chapter.

[4] Section 765.101(9), F.S. "health care information" is defined as: any information, whether oral or recorded in any form or medium, as defined in 45 C.F.R. s. 160.103 and the Health Insurance Portability and Accountability Act of 1996, 42 U.S.C. s. 1320d, as amended, that:
(a) Is created or received by a health care provider, health care facility, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and
(b) Relates to the past, present, or future physical or mental health or condition of the principal; the provision of health care to the principal; or the past, present, or future payment for the provision of health care to the principal.

[5] Section 765.102(3), F.S.

[6] Sections 765.102(1) and (4), 765.204(1), F.S.

[7] Section 765.101(10), F.S. (for anatomical gifts death is defined as incapacity.)

[8] Section 765.107(2), F.S.

[9] Sections 709.2104, 765.202, 765.2035, 765.2038, 765.302(1), 765.303, 765.514(1)(a), F.S.

[10] Sections 765.302(1), 765.202(2), 765.516(1)(b), F.S.

[11] Sections 765.202(2), 765.2035(2), F.S.

[12] Sections 765.202(1), 765.302(1), F.S.

[13] Section 765.2035(1), F.S.

[14] Sections 765.101(1) and (13)(b), F.S. A living will is defined as "a witnessed oral statement made by the principal expressing the principal's instructions concerning life-prolonging procedures."

written) revocation and amendment is recognized for all forms of advance directives,[15] other than a durable power of attorney, which must be amended or revoked in writing. [16] For an oral (or written) revocation or amendment to be effective, it must be communicated to the surrogate, health care provider, or facility.[17,18]

Types of Advance Directives

Under ch. 765, F.S., there are described three types of advance directives: (1) designation of health care surrogate, (2) living will, and (3) anatomical gifts.[19] Chapter 765, F.S., also describes rights and procedures for a durable power of attorney under ch. 709, F.S.[20] Another type of advance directive document is a Do Not Resuscitate Order (DNRO) under the Raymond H. Alexander, M.D. Emergency Medical Services Transportation Act.

Designation of Health Surrogate

The designation of a health surrogate is authorized under the Florida Health Care Surrogate Act, found in part II of ch. 765, F.S. It provides for the designation of an adult individual to make health care decisions and receive health care information for the signing patient. The Act contains suggested forms for designation of a surrogate for an adult[21] and for a minor.[22] The patient can designate whether the surrogate's authority operates immediately or upon the determination of incapacity by his or her primary physician.[23]

If the patient does not choose immediate authorization for the surrogate's authority, there must be a determination of incapacity before the designation becomes operative.[24] Without a determination of incapacity, the patient's wishes are controlling.[25] An inference of incapacity is not permitted from a patient's voluntary or involuntary hospitalization for mental illness or because the patient has intellectual disabilities.[26] Incapacity is determined by the primary or attending physician making an evaluation, and such physician must enter that evaluation into the patient's medical record. If the evaluating physician has a question as to whether the patient lacks capacity, another physician will also evaluate the patient. If both physicians agree, then that evaluation is entered into the medical record for the patient. The health care facility must then notify the applicable surrogate or delegated attorney in writing that his or her authority under the instrument has commenced.[27] The determination of incapacity is only as to health care decisions

[15] Section 765.104(1)(c), F.S.
[16] Section 709.2110(1), F.S.
[17] Section 765.104(3), F.S.
[18] Section 765.516(1)(b), F.S. To orally revoke anatomical gift, it must be revoked "in the presence of two witnesses (one who is not a family member) and is communicated to the donor's family, attorney or donee . . ."
[19] Section 765.101(1), F.S.
[20] Sections 765.101(17), 765.1103(1), 765.204(2) and (4), F.S.
[21] Section 765.203, F.S.
[22] Section 765.2038, F.S.
[23] Sections 765.202(6), 765.204(4), F.S.
[24] Sections 765.101(21), 765.204(2), F.S.
[25] Section 765.204(1), F.S.
[26] *Id.*
[27] Section 765.204(2), F.S.

and is not a finding as to capacity for other purposes.[28] If the patient regains capacity, the surrogacy or agency ceases.[29]

The surrogate's responsibility is to make decisions in accordance with the patient's instructions and limitations.[30] The surrogate, if there are no limitations, can make the full range of health care decisions for the patient.[31] This authority includes the ability to sign DNROs and provide informed consent for the patient.[32] The surrogate has also the full authority to all health information concerning the patient and to use such information to ensure continuity of care and as needed to provide for the admission, discharge, or transfer of the patient to any health care facility or other facility.[33] The surrogate also has authority to apply for public benefits, e.g. Medicare and Medicaid, on behalf of the patient. [34] The standards applicable to the surrogate's duties are: (1) to only make decisions which the surrogate believes the patient would make under the circumstances, or (2) if there is no indication of the patient's desires, then what is in the best interests of the patient.[35]

If there is no living will, and there is no limitation on the surrogate's authority to consent to withholding or withdrawing life-prolonging care, the surrogate is authorized to provide such informed consent. Prior to providing such health care decision, the surrogate must be satisfied that: (1) the patient has an end-stage condition, is in a persistent vegetative stage, or is terminally ill and (2) the patient has no reasonable medical probability of recovering the capacity to make his or her own decision.[36]

Living Will

Living wills are authorized under the Life-Prolonging Procedure Act, found in part III of ch. 765, F.S. This advance directive is a written declaration by the patient as to the providing, withholding, or withdrawal of life-prolonging care.[37] The Act provides for a statutory form of living will. [38] It is possible for the patient to designate in the living will his or her health care surrogate to provide express informed consent for withholding, withdrawal, or continuation of life-prolonging care. [39]

To become operative, a living will requires a determination that the patient (1) has a terminal condition, (2) has an end-stage condition, or (3) is in a persistent vegetative state.[40] Each of these terms is defined in the Act.[41] There must also be a determination that the patient does not have a

[28] Section 765.204(5), F.S.
[29] Section 765.204(3), F.S.
[30] Section 765.205(1), F.S.
[31] Section 765.205(1)(b), and (c), F.S.
[32] *Id.*
[33] Section 765.205(2), F.S.
[34] Section 765.205(1)(e), F.S.
[35] Section 765.205(1)(b), F.S.
[36] Section 765.305(2), F.S.
[37] Section 765.302(1), F.S.
[38] Section 765.303, F.S.
[39] *Id.*
[40] Section 765.306, F.S.
[41] Section 765.101(4), (15) and (22), F.S.

reasonable medical probability of regaining capacity sufficient to exercise his or her own decision making.[42] There must be a finding in the patient's medical record by the primary care physician and at least one other consulting physician that one or more of such conditions exist. Each physician must conduct a separate examination. [43] Once such examinations, findings, medical chart entries, and physician signatures are made, life-prolonging procedures may be withdrawn or withheld pursuant to the terms of the living will.

Anatomical Gifts

Anatomical gifts are authorized under part V of ch. 765, F.S. This advance directive consists of the patient making an anatomical gift of his or her entire body or parts of it.[44] Methods of making the gift are by (1) signing an organ or tissue donor card, (2) registering online with a donor registry, (3) signing an intent to donate on the patient's driver license or identification application, (4) expressing an intent to donate in a living will or other advance directive, (5) a will which includes a provision to donate, or (6) any other writing witnessed by two persons.[45] The Act provides a suggested form of "other writing" known as a Uniform Donor Card. [46] The patient may specifically designate an individual or procurement organization for the gift.[47]

The decision to make an anatomical gift, which is not revoked by the donor, cannot be overridden by any other person and is considered irrevocable.[48] If there is no designation of a gift or notice of a contrary indication by the donor/decedent, then the designated health care surrogate can make the gift.[49] And, if there is no designated health care surrogate, and no contrary indication by the donor/decedent, then in the following order of priority, the following persons can make the gift: (1) the spouse, (2) an adult son or daughter, (3) either parent, (4) an adult brother or sister, (5) an adult grandchild, (6) a grandparent, (7) a close personal friend as defined in s. 765.101(h), F.S., (8) a guardian of the decedent at the time of his or her death, or (9) a representative ad litem appointed by a court.[50]

Durable Power of Attorney

A durable power of attorney is not specifically defined in ch. 765, F.S. It is rather defined in the Florida Power of Attorney Act, found in part II of ch. 709, F.S. A power of attorney is broadly defined as "a writing that grants authority to an agent to act in the place of the principal, whether or not the term is used in that writing."[51] A power of attorney authorizes the adult person designated as an agent to make the same decisions and engage in the same actions as the principal as to the specific authority granted in written document. [52] A power of attorney

[42] Section 765.304(2)(a), F.S.
[43] Section 765.306, F.S.
[44] Section 765.512, F.S.
[45] Section 765.514(1), F.S.
[46] Section 765.514(1)(f), F.S.
[47] Section 765.514(2), F.S.
[48] Section 765.512(1)(a), F.S.
[49] Section 765.512(2), F.S.
[50] Section 765.512(3), F.S.
[51] Section 709.2102(9), F.S.
[52] Section 709.2201, F.S.

terminates if the principal becomes incapacitated.[53] However, a power of attorney which is "durable" does not terminate upon the principal's incapacity. [54] A power of attorney is deemed durable if it contains the words "This durable power of attorney is not terminated by subsequent incapacity of the principal except as provided in ch. 709, F.S.," or similar words that show the principal's intent that the authority conferred is exercisable notwithstanding the principal's subsequent incapacity."[55]

For a power of attorney to be properly executed, it (1) must be signed by the principal, (2) witnessed by two disinterested subscribing witnesses, and (3) acknowledged before a notary public.[56] If the principal is physically unable to sign, the notary public who acknowledges the principal's acknowledgement may sign the principal's name on the instrument and make initials required to acknowledge specific powers.[57] The signing and initialing notary must write the statement "Signature or initials affixed by the notary pursuant to s. 709.2202(2), F.S.," below each signature or initial that the notary writes on behalf of the principal."[58]

The ability to make health decisions or obtain health information on behalf of the principal is recognized if enumerated in the durable power of attorney.[59] Chapter 765, F.S., recognizes durable powers of attorney and the authority of the designated agent.[60] The subsequent designation of health care surrogate does not revoke the decision making authority of an agent under a previous durable power of attorney, unless there is a conflict between the two, in which case the health care surrogate designation has priority.[61] If the durable power of attorney is executed after the designation of health care surrogate, then the durable power of attorney has priority. The power of attorney can also designate the order of priority between the two instruments.[62] A durable power of attorney can only be revoked in writing.[63]

Do-Not-Resuscitate Order (DNRO)

The DNRO is not specifically defined in ch. 765, F.S. It is rather defined in the Raymond H. Alexander, M.D. Emergency Medical Services Transportation Act, found in part III of ch. 401, F.S. This Act recognizes the circumstance and procedures by which emergency technicians may honor DNROs from a patient's physician. The Act directs the Department of Health (DOH) to adopt rules to provide such circumstances and procedures.[64] The Act also requires the DOH, in consultation with the Department of Elder Affairs and the Agency for Health Care Administration (AHCA), to "develop a standardized do-not-resuscitate identification system with devices that signify, when carried or worn, that the possessor is a

[53] Section 709.2109(1)(b), F.S.
[54] Section 709.2104, F.S.
[55] *Id.*
[56] Section 709.2105(2), F.S.
[57] Sections 709.2105(2), 709.2202, F.S.
[58] Section 709.2202(2)(c), F.S.
[59] Section 709.2201(2)(c), F.S.
[60] Sections 765.101(17), 765.1103(1), 765.204(2) and (4), F.S.
[61] Section 709.2109(3)(b), F.S.
[62] *Id.*
[63] Section 709.2110(1), F.S.
[64] Section 401.35(4), F.S.

patient for whom a physician or physician assistant has issued an order not to administer cardiopulmonary resuscitation." [65]

The DOH has adopted in rule a specific form that is required to be used.[66] The DOH rule states the form must be printed on yellow paper for it to be honored.[67, 68] The form also must be signed by the patient's physician, autonomous advanced practice registered nurse (APRN), or physician assistant, and the patient, patient's surrogate, proxy, minor's principal, a guardian under s. 744.102, F.S., or agent under a durable power of attorney.[69] There is no witness requirement or other execution formalities required. The patient has the ability to revoke the form orally, in writing, or by failing to present the form, or by physically destroying the form.[70] To satisfy the "identification with device" portion of the statute, there is a portion of the form that is a recognized wallet card, which is at the bottom of the form and states "Cut along line and fold in half to create DNRO Device (wallet card)."[71]

Absence of Advance Directive/Health Care Proxy

In the event a patient is incapacitated or is developmentally disabled and has no advance directive or the designated surrogate is no longer available (whether voluntarily or involuntarily), part IV of ch. 765, F.S., provides for the appointment of a proxy.[72] The statute provides the following individuals in descending order of priority may be deemed appointed to make health care decisions and receive health care information on behalf of the patient:

- The judicially appointed guardian of the patient or the guardian advocate of the person having a developmental disability as defined in s. 393.063, F.S., who has been authorized to consent to medical treatment, if such guardian has previously been appointed; however, this paragraph shall not be construed to require such appointment before a treatment decision can be made under this subsection;
- The patient's spouse;
- An adult child of the patient, or if the patient has more than one adult child, a majority of the adult children who are reasonably available for consultation;
- A parent of the patient;
- The adult sibling of the patient or, if the patient has more than one sibling, a majority of the adult siblings who are reasonably available for consultation;
- An adult relative of the patient who has exhibited special care and concern for the patient and who has maintained regular contact with the patient and who is familiar with the patient's activities, health, and religious or moral beliefs;
- A close friend of the patient; or
- A clinical social worker licensed pursuant to ch. 491, F.S., or who is a graduate of a court-approved guardianship program.

[65] Section 401.45(3)(c), F.S.
[66] The DNRO form is *available at:* https://www.floridahealth.gov/about/patient-rights-and-safety/do-not-resuscitate/_documents/dnro.pdf (last visited Dec. 04, 2025).
[67] Rule 64J-2.018(5)(a), F.A.C.
[68] Rule 64B8-9.016, the Board of Medicine recognizes that a doctor can rely and implement such a DNRO.
[69] Rule 64J-2.018(6), F.A.C.
[70] Rule 64J-2.018(9), F.A.C.
[71] Rule 64J-2.018(1)(b), F.A.C.
[72] Section 765.401, F.S.

Such a proxy must be selected by the facility's bioethics committee and must not be employed by the provider. If the provider does not have a bioethics committee, then such a proxy may be chosen through an arrangement with the bioethics committee of another provider. The proxy will be notified that, upon request, the provider will make available a second physician, not involved in the patient's care, to assist the proxy in evaluating treatment.[73,74] The facility's bioethics committee will review any decision to withdraw or withhold life-prolonging procedures. The medical record of the patient must contain documentation of efforts to locate proxies of higher priority.[75]

The responsibility and authority of the proxy is the same as a health care surrogate.[76] The proxy, in making health care decisions, is to follow the following standards: (1) based on informed consent, (2) what the proxy reasonably believes would have been the patient's decision under the circumstances, and (3) if there is no indication on what the patient would choose, then what is in the patient's best interest.[77] For decisions to withhold or withdraw life-prolonging procedures, the proxy's standards are clear and convincing evidence of what the patient would have chosen or, if there is no indication what the patient would choose, what is in the best interest of the patient.[78] The proxy must also have the findings of the primary physician and other consulting physician of (1) a terminal condition, an end-stage condition, or the patient is in a persistent vegetative state, and (2) the patient has no reasonable medical probability of recovering the capacity to make his or her own decision.[79]

Persistent Vegetative State

A patient is in a "persistent vegetative state" when he or she is in a permanent and irreversible condition of unconsciousness in which there is:

- The absence of voluntary action or cognitive behavior of any kind.
- An inability to communicate or interact purposefully with the environment."[80]

This finding is to be determined by the person's primary physician utilizing currently accepted medical standards.[81] If such a person does not have any advance directive, there is no evidence of what the person would want under such situation, and, after reasonable diligent inquiry, no family or friends can be made available as a proxy, then the following procedures are to be followed:

- A guardian is appointed by a court, with authority to make medical decisions and who is charged to consider the best interests of the patient.

[73] Section 765.401(1), F.S.
[74] For a minor the order of priority is: The stepparent; the grandparent of the minor; an adult brother or sister of the minor; an adult aunt or uncle of the minor. *See* ss. 765.401(4) and 743.0645(2)(a), F.S.
[75] Section 765.401(1)(h), F.S.
[76] Section 765.401(3), F.S.
[77] Section 765.401(2), F.S.
[78] Section 765.401(3), F.S.
[79] *Id*.
[80] Section 765.101(15), F.S.
[81] Section 765.404, F.S.

- The guardian and bioethics committee of the health care facility, in consultation with the primary physician, may conclude the patient's condition is permanent, there is no reasonable medical probability of recovery, and it is in the best interests of the patient to withdraw or withhold life-prolonging procedures.[82,83]

Civil and Other liability

Health care practitioners and health care facilities are protected from any civil or other legal jeopardy by following the instructions in an advance directive.[84] A surrogate, health care provider, or health care facility is not subject to civil or criminal liability for failing to act on an advance directive, amendment or revocation, unless they have actual notice of such document.[85] The responsibility to provide notice of the existence of an advance directive is on the patient,[86] provided, however, such documentation may be delivered by any other person if the patient is incapacitated. While a health care provider or health care facility cannot require a patient to sign an advance directive, they are required to document and place in the patient's record any advance directive and have such advance directive travel with the patient's medical record.[87]

For a durable power of attorney, there is no specific statutory protection for civil or other liability.[88] The agent is deemed to be acting as a fiduciary.[89]

If presented with the DNRO form on yellow paper, emergency medical staff and physicians are recognized as not subject to criminal or civil liability.[90]

There is also immunity for carrying out any instruction in connection with health care decisions on a patient's behalf by a surrogate or proxy which is in compliance with the provisions of ch. 765, F.S.,[91] i.e. in compliance with a written advance directive, if any, and the requisite standards of wishes of the patient (if known), determination of incapacity, and findings to support a denial or withdrawal of life-prolonging care. Also, there is immunity for a health care facility and individual members of its ethics committee on the decision to withhold or withdraw life-prolonging care when a person is in a persistent vegetative state.[92]

However, if it can be shown by a preponderance of evidence that the person or facility did not act in good faith, then the immunity from liability may not be available.[93]

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[82] Section 765.404(1) and (2), F.S.
[83] If there is no medical ethics committee at the facility, the facility must have an arrangement with the medical ethics committee of another facility or with a community-based ethics committee approved by the Florida Bioethics Network. *See* s. 765.404(2)(h), F.S.
[84] Sections 765.109(1), 765.302(2), 765.517(5), F.S.
[85] Section 765.104(3), F.S.
[86] Sections 765.302(2), 765.512(1)(a), F.S.
[87] Sections 765.110(1) and (2), 765.302(2), F.S.
[88] Section 709.2119(5), F.S. A third party who acts on reliance on a durable power of attorney is to be held harmless by the principal or principal's estate. Section 765.109, F.S., may provide some health care provider or facility immunity, if implementing portions of ch. 765, F.S., as to durable powers of attorney.
[89] Section 709.2114(1), F.S.
[90] Section 401.45(3)(b), F.S.
[91] Section 765.109(1), F.S.
[92] Section 765.404(2), F.S.
[93] Section 765.109(2), F.S.

The terms of a living will establish a rebuttable presumption of clear and convincing evidence of the patient's wishes.[94] A written designation of an adult or minor health care surrogate establishes a clear and rebuttable presumption of the patient's designation of the surrogate.[95]

There is an affirmative duty by the health care practitioner and health care facility to inform and comply with instructions of the patient, surrogate, proxy, court appointed guardian, agent under a durable power of attorney, or patient's physician as to pain management and palliative care.[96]

Court Intervention and Review

Generally, the provisions of the various acts are self-operating and operationalized among the parties. However, there are procedures for court appointed guardians or judicial review of document interpretations or decisions made.

A court appointed guardian must be specifically delegated authority by the court to make health care decisions on behalf of the patient.[97] For purposes of mental health treatment, a surrogate may be separately designated by the patient; however, unless the designation states otherwise, the designated surrogate has the authority to make choices as mental health treatment.[98] Nevertheless, before a surrogate's consent to mental health treatment is effective, there must be a court determination of incompetency and appointment of a guardian advocate under s. 394.4598, F.S.[99]

In addition, health care decision as to abortion, sterilization, electroshock therapy, psychosurgery, experimental treatments that have not been approved by a federally approved institutional review board in accordance with 45 C.F.R. part 46 or 21 C.F.R. part 56, voluntary admission to a mental health facility, or withholding or withdrawing life-prolonging procedures from a pregnant patient prior to viability as defined in s. 390.0111(4), F.S., can only be made by a surrogate or proxy, with approval of a court, and if the patient originally authorized such decision making in writing [100] In all instances, the court may appoint a guardian in addition to a surrogate; however, the surrogate can continue to make health care decisions unless the court modifies or revokes the authority of the surrogate, and the court may require reporting of the

[94] Section 765.302(3), F.S.
[95] Sections 765.202(8) and 765.2035(7), F.S.
[96] Section 765.1103, F.S.
[97] Sections 765.1103(1), 765.404(1), F.S. In addition, unless a patient authorizes, in writing: Abortion, sterilization, electroshock therapy, psychosurgery, experimental treatments that have not been approved by a federally approved institutional review board in accordance with 45 C.F.R. part 46 or 21 C.F.R. part 56, voluntary admission to a mental health facility, or withholding or withdrawing life-prolonging procedures from a pregnant patient prior to viability as defined in s. 390.0111(4), such health care decisions can only be made by a surrogate or proxy, with approval of a court.
[98] Section 765.202(5), F.S. The same applies to minors. *See* section 765.2035(5), F.S.
[99] Section 765.202(5), F.S.
[100] Section 765.113, F.S.

patient's health care status to the guardian.[101] A court may also appoint a representative ad litem for purposes of resolving issues concerning anatomical gifts.[102,103]

There is always the general ability to seek judicial review in probate court or other court of competent jurisdiction as to documentation and decisions.[104] Specific authorization is also provided to pursue a probate petition under Rule 5.900, Florida Rules of Probate Procedures.[105] The category of matters which may pursued under such a petition are:

- The surrogate or proxy's decision is not in accord with the patient's known desires or ch. 765, F.S.;
- The advance directive is ambiguous, or the patient has changed his or her mind after execution of the advance directive;
- The surrogate or proxy was improperly designated or appointed, or the designation of the surrogate is no longer effective or has been revoked;
- The surrogate or proxy has failed to discharge duties, or incapacity or illness renders the surrogate or proxy incapable of discharging duties;
- The surrogate or proxy has abused his or her powers; or
- The patient has sufficient capacity to make his or her own health care decisions.

Section 765.105, F.S., is not available to contest a decision of a surrogate who has immediate authority and the patient is not incapacitated.[106] The petition may be pursued by "[t]he patient's family, the health care facility, or the primary physician, or any other interested person who may reasonably be expected to be directly affected by the surrogate or proxy's decision . . ."[107]

For living wills, it is recognized that the primary physician may proceed in accordance with such living will as to matters concerning life-prolonging procedures and the consent of a designated health care surrogate if one is appointed. However, if there is a dispute, the primary physician cannot take any action to withdraw the life-prolonging procedures for seven days to allow the filing of probate petition. If a probate petition is not filed, then the physician may proceed with implementing the living will.[108]

Medical Records and Orders

Medical professionals are required to keep medical records of the patients they serve. Medical records as defined by statute are required to identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories;

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[101] Section 765.205(3), F.S.
[102] Section 765.512(3)(i), F.S.
[103] In addition, a qualified individual of an anatomical gift may bring an action for injunctive or equitable relief against the health care practitioner, health care facility or other entity responsible for acquisition, delivery or allocation of the anatomical gifts. *See* section 765.523(6), F.S.
[104] Section 765.106. F.S. *See* also, Fla. Prob. R. 5.900, Expedited Judicial Intervention Concerning Medical Treatment.
[105] Section 765.105(1), F.S.
[106] Section 765.105(2), F.S.
[107] Section 765.105(1), F.S.
[108] Section 765.304(1), F.S.

examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.[109]

The purpose of patient/medical records are to:

- Serve as a basis for planning patient care and for continuity in the evaluation of the patient's condition and treatment.
- Furnish documentary evidence of the course of the patient's medical evaluation, treatment, and change in condition.
- Document communication between the practitioner responsible for the patient and any other health care professional who contributes to the patient's care.
- Assist in protecting the legal interest of the patient, the hospital, and the practitioner responsible for the patient.

A licensed physician must maintain patient medical records in English, in a legible manner, and with sufficient detail to clearly demonstrate why a course of treatment was undertaken.[110]

Advance directives must be maintained in medical records if a health care facility or practitioner is made aware of the advance directive by the patient or another person.[111]

When a patient is in a health care facility, what normally occurs with most end-of-life care is as a result of physician orders and established clinical protocols. It has been recognized by the federal Centers for Medicare & Medicaid Services that health care providers can deliver services, pursuant to "standing orders" placed in the medical record.[112] Standing orders are acceptable and can be part of the medical record if they improve efficiency in care delivery, reduce delays in treatment, and enhance patient safety.[113] Standing orders must be evidence-based or follow nationally recognized guidelines, approved by medical staff and clinical leadership, and signed, dated, and authenticated by the ordering physician; and there must be documentation of compliance and periodic review.[114]

Patient-Directed Medical Order (PDMO)

There has been an evolving trend to recognize as an advance directive a comprehensive standing medical order that is developed for an individual facing a serious end-of-life scenario, a chronic

[109] Section 458.331(1)(m), F.S., (as to physicians); section 459.015(1)(o), F.S., (as to osteopathic physicians); section 464.018(1)(s)(5), F.S., (as to advanced registered nurse practitioners); section 464.2035(3), F.S., (as to certified nursing assistant); section 395.3015, F.S., and Rule 59A-3.270 F.A.C. (as to hospitals); section 400.141(1)(j), F.S., and Rule 59A-118, F.A.C. (as to nursing homes).
[110] Rule 64B8-9.003, F.A.C.
[111] Sections 765.110(1) and (2), 765.302(2), F.S. *See* also Patient Self- Determination Act of 1990, 42 U.S.C. §1395cc(f) (as to Medicare providers) and 42 U.S.C §1396a(w) (as to state Medicaid Plans), section 765.110, F.S., essentially incorporates and operationalizes these federal requirements.
[112] Centers for Medicare & Medicaid Services, State Operations Manual, Appendix A – Survey Protocol, Regulations and Interpretive Guidelines for Hospitals, Rev. 75, Tag A-409, (Effective 2-21-20), *available at:* https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf (last visited Dec. 04, 2025).
[113] NCQAC Advisory Opinion 6.0 Standing Orders and Verbal Orders (2014), *available at:* https://doh.wa.gov/sites/default/files/legacy/Documents/6000/StandingAndVerbalOrders.pdf (last visited Dec. 04, 2025).
[114] 42 C.F.R. § 482.24(c)(3), Condition of Participation: Medical record services.

condition, or because of advanced frailty.[115] The differences between the advance directives described above and a PDMO are in timing and form of creation.

The timing of a PDMO is close to the medical needs that justify its creation. It is meant to be a set of medical orders based on a person's current health care condition and prognosis. The PDMO is created between the patient (or surrogate, proxy or agent) and the primary physician. Advance directives are usually prepared by the patient, often when there are no immediate medical concerns. The PDMO is meant to complement advance directives and convert broad preferences into definitive orders signed by a health care provider with specific treatments and activities delineated for the conditions that present at that time in the person's life.[116]

Another reason for the need for this type of advance directive is the changing nature of the physician-patient relationship. In the past, many were cared for upon death by a lifelong family physician. Such physician was usually familiar with the patient and his or her family members and would take care of the patient in the appropriate local health care setting. Now, it is not uncommon for a patient to be cared for by a hospitalist or health care provider they are meeting for the first time when facing an end-of-life scenario. The PDMO is a response by which these important discussions can take place and be documented.[117]

There has also been a recognition that most persons do not execute advance directives. Most studies put the range of failure to have advance directives at approximately 66 percent.[118] Also, it is not uncommon that when patients do have advance directives, they are not explicit enough to provide health care professionals with the instructions needed for decisions at that time in the patient's life.[119]

The PDMO requires the health care provider to have a current and detailed discussion of the person's medical condition and options and tends to be a better expression of the patient's current convictions to withholding or withdrawing end-of-life care. It focuses on high-probability events and decisions that need to be made as to the patient's current condition. It may complement an advance directive or operate as the advance directive for individuals who do not already have one. The PDMO is comprehensive as opposed to single-intervention medical orders, e.g. DNRO.[120]

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[115] Gov Facts, DNR Orders and Living Wills: What Every Patient Should Know, *available at:* https://govfacts.org/health-healthcare/patient-rights-advocacy/advance-directives/dnr-orders-and-living-wills-what-every-patient-should-know/, (*last updated Nov. 24, 2025)* (last visited Dec. 04, 2025).
[116] *Id.*
[117] Hickner, MD, Getting it Right at the End of Life, Journal of Family Practice, vol. 66, no. 8 (Aug. 2017).
[118] *Id.* Citing, Yadav Kn, Gabler NB, Cooney E, et al, Approximately One in Three US Adults Completes Any Type of Advance Directive For End-of-Life Care, Health Affairs, 2017;36:1244-1251.
[119] Bomba P, Sabatino C., POLST: An Emerging Model for End-of-Life Care Planning, The Elder Law Report, v. XX, No. 7 (Feb, 2009)
[120] Mitchell J, POLST Complement Advance Directives to Better Honor Patients' Preferences for End-of-Life Care, One Connect, January 2011.

Emerging Trend

California was the first state to pass an advance directive act in 1976. In the early 1990's, the federal government passed the Patient Self- Determination Act of 1990.[121] This federal law has long required health care providers to discuss the availability of advance directives with their patients. It has become a standard part of health care provider and facility medical discussions with patients as to advance directives.[122]

Florida has implemented the communication and availability requirements of the federal Act. Health care providers and facilities have an obligation to inquire of the patient whether they have an advance directive and document such in the medical record.[123] While a health facility or provider must make the patient aware of the availability of advance directives and the facility's policies as to such directives, a health care provider or facility may not condition treatment or admission on the execution or waiver of advance directives or using a particular form.[124] If a health care provider or facility conditions treatment or admission on the signing or waiver of an advance directive, they are subject to discipline of revocation of licensure and a $1,000 fine per violation.[125]

While most, if not all, states have living wills, health care surrogates, or proxies, many states have also adopted the PDMO as an advance directive. Various states have given it the different monikers, such as Physician Orders for Life-Sustaining Treatment (POLST), MOLST (Medical Orders for Life-Sustaining Treatment), POST (Physician Orders for Scope of Treatment), or COLST (Clinician Orders for Life-Sustaining Treatment). Despite the different nomenclature, they are all functionally the same. To date, 32 states have adopted a PDMO-type of advance directive.[126]

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[121] 42 U.S.C. §1395cc(f) (as to Medicare providers) and 42 U.S.C §1396a(w) (as to state Medicaid Plans).
[122] Florida's Medicaid State Plan, has had the same statement of Requirements for Advance Directive, since October of 1991, *available at:* https://ahca.myflorida.com/content/download/4964/file/attachment_4-34-A.pdf (last visited Dec. 04, 2025).
[123] Section 765.110(1), F.S.
[124] Section 765.110(1) and (2), F.S.
[125] Section 765.110(3), F.S.
[126] The following 32 states have adopted similar statutes or regulations: *Alabama* (2016 SB 138, 2018 HB 194, 2018 HB202); *Arkansas* (2017 SB 356); *California* (2008 AB 3000, 2015 SB19, 2015 AB 637); *Colorado* (2010 HB 10-1122, 2013 HB 13-1202, 2019 SB 19-073) ; *Delaware* (2015 HB 64); *District of Columbia* (2015 ACT 21-247); *Georgia* (2015 SB 109); *Hawaii* (2009 HB 1379, 2014 HB 2052); *Idaho* (Idaho Code 39-4515, Idaho Code 39-4516, 2007 39-4512A); *Iowa* (2012 HF 2165); *Illinois* (2014 SB 3076, 2015 SB 1466); *Indiana* (2013 HB 1182, 2018 HB 1119); *Kentucky* (2015 SB 77); *Louisiana* (2010 HB 1485, 2916 SB 360); *Maryland* (2011HB 82); *Massachusetts* (Chapter 268 of the Acts of 2022); *Mississippi* (2014 HB 1014); *Nevada* (2017 NV POLST Legislation); *New Hampshire* (2015 Title X POLST Registry Act); *New Jersey* (2011 Physician Order for Life Sustaining Treatment Act); *New Mexico* (2015 Uniform Health Decisions Act); *New York* (New York MOLST Ethics and Law); *North Carolina* (2007 § 90-21.17); *Ohio* (2016 Use of Medical Order for Life-Sustaining Treatment); *Oklahoma* (2016 HB 3017); *Oregon* (2009 HB 2009, 2017 SB 856); *Rhode Island* (RIGL 23-4.11-1; 2013 R23-4.11); *South Carolina* (2019 Act No. 89); *Tennessee* (2014 Title 68); *Utah* (Rule 31 Provider Order for Life-Sustaining Treatment); *Vermont* (§9708); *Virginia* (Administrative Code 12VAC5-66); *West Virginia* (2016 HB 4334, 2017 SB 1014); *Wyoming* (2015 HB 0162). *available at:* https://polst.org/state-polst-programs/ (last visited Dec. 4, 2025).

III. Effect of Proposed Changes:

Section 1 amends s. 765.101, F.S., and provides that the definition of "advance directive" includes a patient-directed medical order (PDMO).

The bill also defines "patient-directed medical order" to mean a medical order created by the principal (patient) in collaboration with a physician, a physician assistant, or an autonomous APRN which is portable across health care settings and accessible in a voluntary online registry.

The definition of "health care facility" is amended to add an assisted living facility or adult family-care home licensed under ch. 429, F.S.

Section 2 amends the legislative intent provision within s. 765.102, F.S. Current law provides a definition of what palliative care *must* include and specifies 11 required elements. The bill changes "must" to "may" for each of the existing 11 elements and adds that an order not to resuscitate and a PDMO will be respected regardless of the location of care.

Section 3 creates s. 765.3041, F.S., entitled "Patient-directed medical orders."

Form of Order

The bill requires the form for a PDMO to be developed by rule of the DOH. The form may be combined with a DNRO. The form must address medical interventions that may be withheld or withdrawn if they only serve to artificially prolong the process of dying.

The form must clearly express the principal's preferences and instructions for care. The treatments which may be included are all that are available, modified treatments that are not prolonged or burdensome, and comfort measures that do not pursue or continue interventions.

Health care services which provide for care, comfort, or to alleviate pain may not be withheld or withdrawn.

Signature Requirements

The form is to be signed by the principal and the principal's physician, physician assistant or autonomous APRN. There is a substitute signature procedure for a physically-unable principal, the same as provided for the other advance directives authorized under ch. 765, F.S. The principal's signature can be subscribed (in the presence and direction of the principal) by the physician, physician assistant, or autonomous APRN.

If the principal is completely incapacitated, the form may be signed by the principal's surrogate, proxy, attorney in fact under a durable power of attorney, or an appointed guardian with authority to make health care decisions.

The bill authorizes the use of telehealth to provide for the substituted signature of a physically-unable principal. The physician, physician assistant, or autonomous APRN may be present at either location where the telehealth is being conducted.

For any party, electronic signatures are authorized under the bill.

Communications

The bill requires the principal and his or her physician, physician assistant, or autonomous APRN to discuss the principal's medical treatment wishes for withholding or withdrawing medical interventions, and the principal's values and preferences in the event he or she becomes unable to make decisions. These preferences must be included in the form. The discussion must be held in person or using telehealth.

Civil, Criminal and Disciplinary Liability

The bill provides that any physician, physician assistant, or autonomous APRN is not subject to civil, criminal, or disciplinary action or liability for withdrawing or withhold cardiopulmonary resuscitation or other life-prolonging procedure pursuant to a PDMO or DNRO. The bill also provides that such behavior does not constitute negligent or unprofessional conduct.

Section 4 amends s. 395.1041, F.S. to provide that hospital personnel may withhold or withdraw any life-prolonging procedures if presented with a PDMO containing a DNRO or an order to withhold or withdraw such care. The bill also adds such behavior to existing provisions for hospitals and hospital personnel relating to immunity from criminal or civil liability and negligent or unprofessional conduct.

Section 5 amends s. 400.142, F.S., relating to nursing homes to add similar provisions for those facilities and their personnel as the bill adds for hospitals and hospital personnel in Section 4 of the bill.

Section 6 amends s. 400.487, F.S., relating to home health agencies to add similar provisions for those agencies and their personnel as the bill adds for hospitals, hospital personnel, nursing homes, and nursing home personnel in Section 4 and Section 5 of the bill

S**ection 7** amends s. 400.605, F.S., relating to the AHCA's rule-making requirements for hospice services. The bill requires that such rules must include procedures relating to the implementation of a PDMO and a DNRO.

Section 8 amends s. 400.6095, F.S., relating to hospice services to add similar provisions for hospice services personnel as the bill adds for hospital personnel, nursing home personnel, and home health agency personnel in Section 4, Section 5, and Section 6 of the bill.

Section 9 amends s. 400.611, F.S., relating to hospices to make technical and conforming changes.

Section 10 amends s. 401.35, F.S. relating to emergency medical services (EMS) to require the DOH to adopt rules relating to EMS personnel and PDMOs as provided in Section 11 of the bill.

Section 11 amends s. 401.45, F.S., relating to EMS services to add similar provisions for EMS personnel as the bill adds for hospital personnel, nursing home personnel, home health agency personnel, and hospice services personnel in Section 4, Section 5, Section 6, and Section 8 of the

bill. The bill also adds the signature of an autonomous APRN as an appropriate signatory to conform to the bill's earlier provisions relating to autonomous APRNs.

Section 12 amends s. 429.255, F.S., relating to assisted living facilities (ALF) to add similar provisions for those facilities and their personnel as the bill adds for hospitals, hospital personnel, nursing homes, and nursing home personnel in Section 4 and Section 5 of the bill.

S**ection 13** amends s. 429.73, F.S., relating to adult family-care homes to add similar provisions for a person who is licensed to operate an adult family-care home as the bill adds for hospital personnel, nursing home personnel, home health agency personnel, hospice services personnel, and EMS personnel in Section 4, Section 5, Section 6, Section 8, and Section 11 of the bill. The bill embeds these provisions for persons licensed to operate adult family-care homes in the AHCA's existing rule-making requirements for regulating such homes.

Section 14 amends s. 744.4431, F.S., relating to professional guardians to add PDMOs to existing provisions relating to withholding or withdrawing life-prolonging care or executing a DNRO.

Section 15 amends s. 752.001, F.S., to make a technical amendment to the definition of "persistent vegetative state."

Section 16 amends s. 765.110, F.S., to add PDMOs and DNROs to existing requirements for health care facilities to provide each patient with written information concerning the individual's rights relating to advance directives. The bill also adds ALFs and adult family-care homes to the list of entities for which the AHCA is required to adopt rules relating to the implementation of s. 765.110, F.S.

Section 17 amends s. 765.204, F.S., to make technical and conforming changes.

Section 18 amends s. 765.205, F.S., relating to surrogates to create a surrogate's authority to provide written consent to a DNRO or a PDMO.

Section 19 amends s. 765.305, F.S., relating to the standards for a surrogate's authority to act in the absence of a living will. The bill requires that before a DNRO or a PDMO may be exercised to forego treatment, the surrogate must be satisfied that the patient has an end-stage condition, has a chronic illness, or is in a persistent vegetative state; and does not have a reasonable medical probability of recovering the capacity to forego treatment on his or her own.

Section 20 creates a non-statutory provision of law requiring the AHCA to create and update a database by which PDMOs may be stored in electronic form by the AHCA if the principal wishes his or her PDMO to be stored in this fashion.

Section 21 provides an effective date of July 1, 2026.

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 requires rulemaking by the DOH to create and adopt the PDMO form. The bill creates a negative fiscal impact relating to the requirement for the AHCA to create and maintain a database for the electronic storage of PDMOs. Neither agency has provided an estimate of fiscal impact, as of this writing.

VI. Technical Deficiencies:

None.

VII. Related Issues:

Section 20 of the bill requires the AHCA to create and maintain a database for the electronic storage of PDMOs. Such documents might contain sensitive personal information regarding private individuals, and it is not clear whether the bill intends for such documents to be part of the public record after the AHCA takes possession of them. As of this writing, no corresponding public record exemption bill has been filed.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 765.101, 765.102, , 395.1041, 400.142, 400.487, 400.605, 400.6095, 400.611, 401.35, 401.45, 429.255, 429.73, 744.4431, 752.001, 765.110, 765.204, 765.205, 765.305.

This bill creates section 765.3041 of the Florida Statutes.

This bill creates one non-statutory section of the Laws of Florida.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.

By Senator Rodriguez

40-00411-26 2026312__

A bill to be entitled

An act relating to patient-directed medical orders; amending s. 765.101, F.S.; revising definitions and defining the term "patient-directed medical order"; amending s. 765.102, F.S.; revising legislative findings and intent; creating s. 765.3041, F.S.; authorizing the execution of a patient-directed medical order for a specified purpose; providing requirements for valid patient-directed medical orders; authorizing the use of telehealth for a specified purpose; requiring that certain health care services be provided to the principal regardless of the decision to withhold or withdraw life-prolonging procedures; authorizing physicians, physician assistants, and advanced practice registered nurses to withhold or withdraw life-prolonging procedures under certain circumstances without penalty; providing construction; amending ss. 395.1041, 400.142, 400.487, 400.605, 400.6095, 400.611, 401.35, 401.45, 429.255, 429.73, 744.4431, 752.001, 765.110, 765.204, 765.205, and 765.305, F.S.; conforming cross-references and provisions to changes made by the act; requiring the Agency for Health Care Administration to create and update a database for the storage of patient-directed medical orders; providing an effective date.

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

Section 1. Present subsections (15) through (22) of section

765.101, Florida Statutes, are redesignated as subsections (16) through (23), respectively, a new subsection (15) is added to that section, and subsections (1) and (7) of that section are amended, to read:

765.101 Definitions.—As used in this chapter:

(1) "Advance directive" means a witnessed written document or oral statement in which instructions are given by a principal or in which the principal's desires are expressed concerning any aspect of the principal's health care or health information, and includes, but is not limited to, the designation of a health care surrogate, a living will, or an anatomical gift made pursuant to part V of this chapter. An advance directive may also include a patient-directed medical order.

(7) "Health care facility" means a hospital, nursing home, hospice, home health agency, or health maintenance organization licensed in this state; a~~, or any~~ facility subject to part I of chapter 394; or an assisted living facility or adult family-care home licensed under chapter 429.

(15) "Patient-directed medical order" means a medical order created by the principal in collaboration with a physician, a physician assistant, or an advanced practice registered nurse registered under s. 464.0123 which is portable across health care settings and accessible in a voluntary online registry.

Section 2. Subsection (6) of section 765.102, Florida Statutes, is amended to read:

765.102 Legislative findings and intent.—

(6) For purposes of this chapter:

(a) Palliative care is the comprehensive management of the physical, psychological, social, spiritual, and existential

needs of patients. Palliative care is especially suited to the care of persons who have incurable or~~,~~ progressive illnesses.

(b) Palliative care may ~~must~~ include:

1. An opportunity to discuss and plan for end-of-life care.

2. Assurance that physical and mental suffering will be carefully attended to.

3. Assurance that preferences for withholding and withdrawing life-sustaining interventions will be honored.

4. Assurance that the personal goals of the dying person will be addressed.

5. Assurance that the dignity of the dying person will be a priority.

6. Assurance that health care providers will not abandon the dying person.

7. Assurance that the burden to family and others will be addressed.

8. Assurance that advance directives for care, orders not to resuscitate executed pursuant to s. 401.45, and patient-directed medical orders executed pursuant to s. 765.3041 will be respected regardless of the location of care.

9. Assurance that organizational mechanisms are in place to evaluate the availability and quality of end-of-life, palliative, and hospice care services, including the evaluation of administrative and regulatory barriers.

10. Assurance that necessary health care services will be provided and that relevant reimbursement policies are available.

11. Assurance that the goals expressed in subparagraphs 1.-10. will be accomplished in a culturally appropriate manner.

Section 3. Section 765.3041, Florida Statutes, is created

to read:

765.3041 Patient-directed medical orders.—

(1) To facilitate a principal's instructions concerning treatment preferences, a patient-directed medical order may be executed in advance to direct the actions of health care providers and health care facilities.

(2) A valid patient-directed medical order must:

(a) Be on a form adopted by rule of the Department of Health and may be combined with an order not to resuscitate executed pursuant to s. 401.45. The form must:

1. Address medical interventions to be withheld or withdrawn when the application of life-prolonging procedures would serve only to prolong artificially the process of dying.

2. Be signed by the principal and the principal's physician, physician assistant, or advanced practice registered nurse registered under s. 464.0123.

a. If the principal is physically unable to sign the form, the physician, physician assistant, or advanced practice registered nurse present at the discussion as required by subparagraph (b)1. may subscribe the principal's signature in the principal's presence and at the principal's direction. If telehealth is used, the physician, physician assistant, or advanced practice registered nurse may be present at either location where telehealth is being administered.

b. If the principal is incapacitated, the form may be signed by the principal's health care surrogate or proxy, court-appointed guardian as provided in chapter 744, or attorney in fact under a durable power of attorney as provided in chapter 709. The court-appointed guardian or attorney in fact must be

delegated authority to make health care decisions on behalf of the principal.

c. All signatures may be electronic signatures.

(b) Clearly express the principal's preferences and instructions for care, which may include all treatments available, modified treatments that are not prolonged or burdensome, or comfort measures that do not pursue or continue interventions.

1. The principal and a physician, a physician assistant, or an advanced practice registered nurse registered under s. 464.0123 must discuss the principal's medical treatment wishes relating to medical interventions to be withheld or withdrawn based on the principal's values and preferences in the event the principal becomes unable to make her or his own decisions.

2. The discussion must be in person and may be conducted using telehealth.

(3) Regardless of the decision to withhold or withdraw life-prolonging procedures, necessary health care services must be provided for the care and comfort of the principal or to alleviate pain.

(4) A physician, a physician assistant, or an advanced practice registered nurse registered under s. 464.0123 may withhold or withdraw cardiopulmonary resuscitation or other life-prolonging procedures if presented with an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to this section which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures. A physician, a physician assistant, or an advanced practice registered nurse registered under s.

464.0123 is not subject to any disciplinary action under s. 456.072 or criminal prosecution or civil liability, or considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures pursuant to such orders. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to this section does not preclude a physician, a physician assistant, or an advanced practice registered nurse registered under s. 464.0123 from withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures as otherwise authorized by law.

Section 4. Paragraph (l) of subsection (3) of section 395.1041, Florida Statutes, is amended to read:

395.1041 Access to and ensurance of emergency services; transfers; patient rights; diversion programs; reports of controlled substance overdoses.—

(3) EMERGENCY SERVICES; DISCRIMINATION; LIABILITY OF FACILITY OR HEALTH CARE PERSONNEL.—

(l) Hospital personnel may withhold or withdraw cardiopulmonary resuscitation or other life-prolonging procedures if presented with an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures. Facility staff and facilities are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, or ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary

resuscitation or other life-prolonging procedures pursuant to such orders ~~an order~~. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures as otherwise authorized ~~permitted~~ by law.

Section 5. Subsection (3) of section 400.142, Florida Statutes, is amended to read:

400.142 Emergency medication kits; orders not to resuscitate and patient-directed medical orders.—

(3) Facility staff may withhold or withdraw cardiopulmonary resuscitation or other life-prolonging procedures if presented with an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures. Facility staff and facilities are not subject to criminal prosecution or civil liability, or considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures pursuant to such orders ~~order~~. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures as otherwise authorized ~~permitted~~ by law.

Section 6. Subsection (7) of section 400.487, Florida Statutes, is amended to read:

400.487 Home health service agreements; physician's, physician assistant's, and advanced practice registered nurse's treatment orders; patient assessment; establishment and review of plan of care; provision of services; orders not to resuscitate and patient-directed medical orders.—

(7) Home health agency personnel may withhold or withdraw cardiopulmonary resuscitation or other life-prolonging procedures if presented with an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures. The agency shall adopt rules providing for the implementation of such orders. Home health personnel and agencies are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, or ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures pursuant to such orders ~~an order~~ and rules adopted by the agency. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures as otherwise authorized by law.

Section 7. Paragraph (e) of subsection (1) of section 400.605, Florida Statutes, is amended to read:

400.605 Administration; forms; fees; rules; inspections; fines.—

(1) The agency shall by rule establish minimum standards

and procedures for a hospice pursuant to this part. The rules must include:

(e) Procedures relating to the implementation of advance ~~advanced~~ directives, patient-directed medical orders executed pursuant to s. 765.3041, and ~~do-not-resuscitate~~ orders not to resuscitate executed pursuant to s. 401.45.

Section 8. Subsection (8) of section 400.6095, Florida Statutes, is amended to read:

400.6095 Patient admission; assessment; plan of care; discharge; death.—

(8) The hospice care team may withhold or withdraw cardiopulmonary resuscitation or other life-prolonging procedures if presented with an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures. The agency shall adopt rules providing for the implementation of such orders. Hospice staff are ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, or ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures pursuant to such orders ~~an order~~ and applicable rules. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures as otherwise authorized ~~permitted~~ by law.

Section 9. Paragraph (b) of subsection (4) of section

400.611, Florida Statutes, is amended to read:

400.611 Interdisciplinary records of care; confidentiality; release of records.—

(4) A hospice may not release a patient's interdisciplinary record or any portion thereof, unless the person requesting the information provides to the hospice:

(b) In the case of an incapacitated patient, a patient authorization executed before ~~prior to~~ the patient's death by the patient's then acting legal guardian, health care surrogate as defined in s. 765.101 ~~s. 765.101(21)~~, health care proxy as defined in s. 765.101 ~~s. 765.101(19)~~, or agent under power of attorney;

Section 10. Subsection (4) of section 401.35, Florida Statutes, is amended to read:

401.35 Rules.—The department shall adopt rules, including definitions of terms, necessary to carry out the purposes of this part.

(4) The rules must establish circumstances and procedures under which emergency medical technicians and paramedics may honor orders not to resuscitate executed pursuant to s. 401.45 or patient-directed medical orders executed pursuant to s. 765.3041 which contain an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures by the patient's physician, physician assistant, or advanced practice registered nurse registered under s. 464.0123 ~~not to resuscitate~~ and the documentation and reporting requirements for handling such orders ~~requests~~.

Section 11. Paragraphs (a) and (b) of subsection (3) of section 401.45, Florida Statutes, are amended to read:

401.45 Denial of emergency treatment; civil liability.—

(3)(a) ~~Resuscitation may be withheld or withdrawn from a patient by~~ An emergency medical technician or paramedic may withhold or withdraw cardiopulmonary resuscitation or other life-prolonging procedures if presented with ~~evidence of~~ an order not to resuscitate executed pursuant to this subsection or a patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures ~~by the patient's physician or physician assistant is presented to the emergency medical technician or paramedic~~. An order not to resuscitate executed pursuant to this subsection or a patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures, to be valid, must be on the form adopted by rule of the department. The form must be signed by the patient's physician, ~~or~~ physician assistant, or advanced practice registered nurse registered under s. 464.0123 and by the patient or, if the patient is incapacitated, the patient's health care surrogate or proxy as provided in chapter 765, court-appointed guardian as provided in chapter 744, or attorney in fact under a durable power of attorney as provided in chapter 709. The court-appointed guardian or attorney in fact must have been delegated authority to make health care decisions on behalf of the patient.

(b) Any licensee, physician, medical director, or emergency medical technician or paramedic who acts under the direction of a medical director is not subject to criminal prosecution or civil liability, and has not engaged in negligent or

unprofessional conduct, as a result of the withholding or withdrawal of cardiopulmonary resuscitation or other life-prolonging procedures from a patient pursuant to this subsection and rules adopted by the department.

Section 12. Subsection (4) of section 429.255, Florida Statutes, is amended to read:

429.255 Use of personnel; emergency care.—

(4) Facility staff may withhold or withdraw cardiopulmonary resuscitation, ~~or~~ the use of an automated external defibrillator, or other life-prolonging procedures if presented with an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures. The agency shall adopt rules providing for the implementation of such orders. Facility staff and facilities are ~~may~~ not ~~be~~ subject to criminal prosecution or civil liability, or ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation, the ~~or~~ use of an automated external defibrillator, or other life-prolonging procedures pursuant to such orders ~~an order~~ and rules adopted by the agency. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation, the ~~or~~ use of an automated external defibrillator, or other life-prolonging procedures as otherwise authorized ~~permitted~~ by law.

Section 13. Subsection (3) of section 429.73, Florida

Statutes, is amended to read:

429.73 Rules and standards relating to adult family-care homes.—

(3) The agency shall adopt rules providing for the implementation of orders not to resuscitate and patient-directed medical orders. The provider may withhold or withdraw cardiopulmonary resuscitation or other life-prolonging procedures if presented with an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures. The provider is ~~shall~~ not ~~be~~ subject to criminal prosecution or civil liability, or ~~nor be~~ considered to have engaged in negligent or unprofessional conduct, for withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures pursuant to such orders ~~an order~~ and applicable rules. The absence of an order not to resuscitate executed pursuant to s. 401.45 or a patient-directed medical order executed pursuant to s. 765.3041 does not preclude a physician from withholding or withdrawing cardiopulmonary resuscitation or other life-prolonging procedures as otherwise authorized by law.

Section 14. Subsections (1), (7), and (8) of section 744.4431, Florida Statutes, are amended to read:

744.4431 Guardianship power regarding life-prolonging procedures.—

(1) Except as provided in this section, decisions by a professional guardian, as defined in s. 744.102, to withhold or withdraw life-prolonging procedures from, or to execute an order

not to resuscitate pursuant to s. 401.45 or a patient-directed medical order pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures for, a ward must be approved by the court. A professional guardian appointed to act on behalf of a ward's person must petition the court pursuant to the Florida Probate Rules for authority to consent to withhold or withdraw life-prolonging procedures or to execute an order not to resuscitate pursuant to s. 401.45 or a patient-directed medical order pursuant to s. 765.3041. Court approval must be obtained before taking such action, except as provided in subsection (7).

(7) Court approval is not required for the following decisions:

(a) A decision to withhold or withdraw life-prolonging procedures made by a professional guardian to whom authority has been granted by the court under s. 744.3115 to carry out the instructions in or to take actions consistent with the ward's advance directive, order not to resuscitate executed pursuant to s. 401.45, or patient-directed medical order executed pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures, as long as there are no known objections from the ward; the ward's attorney; the ward's next of kin, if known; and any other interested persons as the court may direct based on s. 765.105(1).

(b) A decision by a professional guardian who has been delegated health care decisionmaking authority to execute an order not to resuscitate pursuant to s. 401.45 or a patient-directed medical order pursuant to s. 765.3041~~, as described in~~

~~s. 401.45(3)(a)~~, if the ward is in a hospital and the following conditions are met:

1. The ward's primary treating physician and at least one other consulting physician document in the ward's medical record that:

a. There is no reasonable medical probability for recovery from or a cure of the ward's underlying medical condition;

b. The ward is in an end-stage condition, a terminal condition, or a persistent vegetative state as those terms are defined in s. 765.101, and that the ward's death is imminent; and

c. Resuscitation will cause the ward physical harm or additional pain.

2. The professional guardian has notified the ward's next of kin, if known, and any interested persons as the court may direct and the decision is not contrary to the ward's expressed wishes and there are no known objections from the ward; the ward's attorney; the ward's next of kin, if known; or any other interested persons as the court may direct on the basis of s. 765.105(1).

(8) Within 2 business days after executing an order not to resuscitate pursuant to s. 401.45 or a patient-directed medical order pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures ~~under paragraph (7)(b)~~, a professional guardian must notify the court in writing of all of the following:

(a) The date the order not to resuscitate or patient-directed medical order was executed.

(b) The location of the ward when the order not to

resuscitate or patient-directed medical order was executed.

(c) The names of the physicians who documented the ward's condition in the ward's medical record.

Section 15. Subsection (3) of section 752.001, Florida Statutes, is amended to read:

752.001 Definitions.—As used in this chapter, the term:

(3) "Persistent vegetative state" has the same meaning as ~~provided~~ in s. 765.101 ~~s. 765.101(15)~~.

Section 16. Subsections (1) and (4) of section 765.110, Florida Statutes, are amended to read:

765.110 Health care facilities and providers; discipline.—

(1) A health care facility~~, pursuant to Pub. L. No. 101-508, ss. 4206 and 4751,~~ shall provide to each patient written information concerning the individual's rights concerning advance directives, orders not to resuscitate executed pursuant to s. 401.45, or patient-directed medical orders executed pursuant to s. 765.3041 which contain an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures and the health care facility's policies respecting the implementation of such rights, and shall document in the patient's medical records whether ~~or not~~ the individual has executed an advance directive, an order not to resuscitate pursuant to s. 401.45, or a patient-directed medical order pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures.

(4) The Department of Health, in consultation with the Department of Elderly Affairs, for health care providers; the Agency for Health Care Administration for hospitals, hospices,

nursing homes, home health agencies, assisted living facilities, adult family-care homes, and health maintenance organizations; and the Department of Children and Families for facilities subject to part I of chapter 394 shall adopt rules to implement this section.

Section 17. Subsection (3) of section 765.204, Florida Statutes, is amended to read:

765.204 Capacity of principal; procedure.—

(3) The surrogate's authority commences either upon a determination under subsection (2) that the principal lacks capacity or upon a stipulation of such authority pursuant to s. 765.101 ~~s. 765.101(21)~~. Such authority remains in effect until a determination that the principal has regained such capacity, if the authority commenced as a result of incapacity, or until the authority is revoked, if the authority commenced immediately pursuant to s. 765.101 ~~s. 765.101(21)~~. Upon commencement of the surrogate's authority, a surrogate who is not the principal's spouse shall notify the principal's spouse or adult children of the principal's designation of the surrogate. Except if the principal provided immediately exercisable authority to the surrogate pursuant to s. 765.101 ~~s. 765.101(21)~~, in the event that the primary or attending physician determines that the principal has regained capacity, the authority of the surrogate shall cease, but recommences if the principal subsequently loses capacity as determined pursuant to this section. A health care provider is not liable for relying upon health care decisions made by a surrogate while the principal lacks capacity. At any time when a principal lacks capacity, a health care decision made on the principal's behalf by a surrogate is effective to

the same extent as a decision made by the principal. If a principal possesses capacity, health care decisions of the principal take precedence over decisions made by the surrogate that present a material conflict.

Section 18. Paragraph (c) of subsection (1) of section 765.205, Florida Statutes, is amended to read:

765.205 Responsibility of the surrogate.—

(1) The surrogate, in accordance with the principal's instructions, unless such authority has been expressly limited by the principal, shall:

(c) Provide written consent using an appropriate form whenever consent is required, including the execution of an ~~a physician's~~ order not to resuscitate pursuant to s. 401.45 or a patient-directed medical order pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures.

Section 19. Subsection (2) of section 765.305, Florida Statutes, is amended to read:

765.305 Procedure in absence of a living will.—

(2) Before exercising the incompetent patient's right to forego treatment, including the execution of an order not to resuscitate pursuant to s. 401.45 or a patient-directed medical order pursuant to s. 765.3041 which contains an order not to resuscitate or an order to withhold or withdraw life-prolonging procedures, the surrogate must be satisfied that:

(a) The patient does not have a reasonable medical probability of recovering capacity so that the right could be exercised by the patient.

(b) The patient has an end-stage condition, the patient is

in a persistent vegetative state, or the patient's physical condition is terminal.

Section 20. The Agency for Health Care Administration shall create and update a database for the storage of patient-directed medical orders, which shall be stored solely at the option of the patient in electronic form by the agency.

Section 21. This act shall take effect July 1, 2026.

The Florida Senate

Committee Agenda Request

To: Senator Colleen Burton, Chair
Committee on Health Policy

Subject: Committee Agenda Request

Date: December 1, 2025

I respectfully request that **SB 312**, relating to Patient-directed Medical Orders, be placed on the:

☒ committee agenda at your earliest possible convenience.

☐ next committee agenda.

Senator Ana Maria Rodriguez
Florida Senate, District 40

File signed original with committee office

S-020 (03/2004)

The Florida Senate

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Dec. 9, 2025
Meeting Date

Health Policy
Committee

SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

Name Alexis Hall

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City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

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Health Policy
Committee

SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

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City State Zip

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Committee

SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

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City State Zip

Speaking: ☐ For ☑ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☑ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

Florida Right to Life

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Health Policy
Committee

SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

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City State Zip

Speaking: [X] For [ ] Against [ ] Information **OR** Waive Speaking: [ ] In Support [ ] Against

PLEASE CHECK ONE OF THE FOLLOWING:

[X] I am appearing without compensation or sponsorship.

[ ] I am a registered lobbyist, representing:

[ ] I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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Committee

SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

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City State Zip

Reset Form

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

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City State Zip

Reset Form

Speaking: ☑ For ☐ Against ☐ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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SB 312
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Amendment Barcode (if applicable)

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Winter Park, FL 32789
City State Zip

Speaking: [X] For [ ] Against [ ] Information **OR** Waive Speaking: [ ] In Support [ ] Against

PLEASE CHECK ONE OF THE FOLLOWING:

[X] I am appearing without compensation or sponsorship.

[ ] I am a registered lobbyist, representing:

[ ] I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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December 9, 2025
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Health Policy
Committee

SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

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Address 120 S. Monroe St Email
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Tallahassee FL 32301
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing: Florida Nurse Practioner Network

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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Health Policy
Committee

SB312
Bill Number or Topic

Amendment Barcode (if applicable)

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City *State* *Zip*

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
Florida Osteopathic Medical Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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SB 312
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Amendment Barcode (if applicable)

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Reset Form

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:
FL Hospice&Palliative Care Assoc

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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312
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Amendment Barcode (if applicable)

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Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☑ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

Florida Chapter, American College of Physicians

While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

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S-001 (08/10/2021)

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
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Dec 9, 2025
Meeting Date

(s) Health Policy
Committee

SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

Name Erin Ballas

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Address 2020 New Dawn Rd 730 E. Park Ave
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Email erinballas@paconsultants.com

Tallahassee FL 32301
City State Zip

Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☒ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☒ I am a registered lobbyist, representing: Florida Nurses Association

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

Dec. 9, 2025
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Health Policy
Committee

The Florida Senate

APPEARANCE RECORD

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Senate professional staff conducting the meeting

SB 312
Bill Number or Topic

Amendment Barcode (if applicable)

Name Kathleen Wilson

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Speaking: ☐ For ☐ Against ☐ Information **OR** Waive Speaking: ☑ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☑ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

☐ I am not a lobbyist, but received something of value for my appearance (travel, meals, lodging, etc.), sponsored by:

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S-001 (08/10/2021)

Senate Health Policy Committee

Advancing Cancer Research and Innovation: Implementation of SB 7072 (2024) and SB 2514 (2025)

Florida Department of Health

December 9, 2025

Emma Spencer, PhD, MPH
Director, Division of Public Health Statistics and Performance Management

Florida HEALTH

Presentation Overview

Purpose: Implementation of SB 7072 (2024) and SB 2514 (2025)

- **Legislative Context**
- **Key Initiatives:** Cancer Connect Collaborative, Cancer Innovation Fund, and Cancer Connect Collaborative Research Incubator
- **Strategic Goals:**
  - Accelerate cancer research and treatment innovation
  - Improve access to clinical trials
  - Strengthen Florida's leadership in cancer care
  - Foster sustainable, collaborative infrastructure

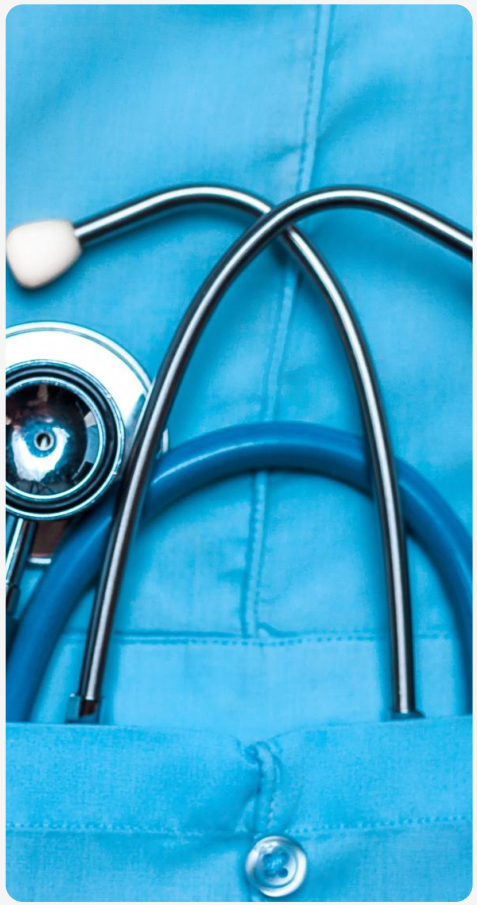
Legislative Background

SB 7072 (2024), Section 1

- Establishes the Cancer Connect Collaborative
- Revises the Casey DeSantis Cancer Research Program

SB 2514 (2025), Section 2

- Amends section 381.915(9), F.S., Cancer Innovation Fund
- Creates section 381.915(12), F.S., Research Incubator



Cancer Connect Collaborative

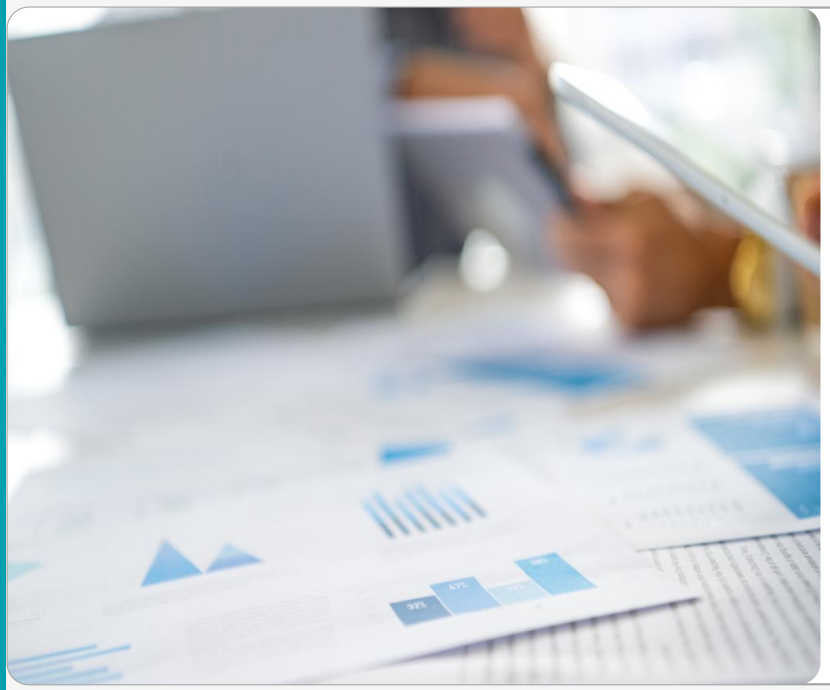
Purpose

Break down silos between researchers, providers, and facilities

Key Functions

- Develop long-range cancer research plan
  - Submitted December 1, 2024, included recommendations to:
    - Expand funding opportunities
    - Create a statewide entity with the purpose of issuing cancer research funding and providing oversight and transparency of data, best practices, and patient care in Florida
- Advise on grant awards from the Cancer Innovation Fund
- Recommend best practices and policy changes

Collaborative Activities



FY 2024-2026

- Stakeholder engagement and planning
- Data infrastructure improvements
- Annual reporting to Governor and Legislature

Cancer Innovation Fund

Created in FY 23-24

$60 million available in FY 2025-26 (3rd year)

Supports

- Clinical trials
- Nutrition-based prevention
- Drug repurposing
- Rapid 12-month research cycles

Rolling application process began on September 29, 2025

Innovation Fund Impact

FY 2023-2025
$80 Million Awarded
95 Awardees

FY 2024-25

- 261 applicants requested more than $216 million in funding
- Awarded $60 million for 65 groundbreaking projects, driving progress in targeted therapies, early detection tools, and innovative supportive care approaches
- Grant awards distributed across 28 institutions, encompassing research for more than16 distinct cancer types

FY 2025-26, Funding Opportunity Announcement Emphasizes:

- Immediate clinical translation
- Rapid research advancement
- Health care delivery innovation
- Prevention and accessibility innovation

Cancer Connect Collaborative Research Incubator

- Established under section 381.915(12), F.S.
- 5-year focus (2025-30) is pediatric cancer
- $30 million allocated in FY 2025-26
- Oversight by the Cancer Connect Collaborative

Research Incubator Implementation

Eligible Applicants

Florida-based children's specialty hospitals treating pediatric cancer

Priorities

- Increase clinical trial participation
- Support education and awareness
- Foster academic-community partnerships

Awardees

- Johns Hopkins All Children’s Hospital
- Wolfson Children’s Hospital
- Nemours Children’s Hospital
- Nicklaus Children’s Hospital

Awarded Incubator Projects

Nicklaus Children's Health System: Establish a comprehensive Phase I Clinical Trials Unit and statewide pediatric cancer research infrastructure.

Johns Hopkins All Children's Hospital: Establish a comprehensive statewide pediatric cancer research and care incubator program serving as Florida's only Children’s Oncology Group Early Phase Clinical Trials site.

Wolfson Children's Hospital: Build a comprehensive pediatric oncology infrastructure across two strategic areas, clinical operations and research foundation.

Nemours Children's Hospital: Develop a comprehensive statewide pediatric cancer program addressing critical care gaps, particularly in underserved populations.

Reporting Requirements

- Section 381.915(9)(e), F.S., annual report for Cancer Innovation Fund outcomes, starting in 2025
- Section 381.915(12)(c), F.S., Incubator progress report due annually, starting in 2026, that must include:
  - Details of all results of the research conducted with incubator funding that has been completed or in-progress
  - Evaluation of all research conducted with incubator funding during the five fiscal years preceding the report

Timeline of Key Milestones

FY 2024-25: November 4, 2024
Florida Cancer Innovation Fund Applications Year 2 Opened

FY 2024-25: December 1, 2024
Long-Range Plan Submitted

FY 2025-26: September 29, 2025
Florida Cancer Innovation Fund Applications Year 3 Opened

FY 2025-26: March-June 2026
Expected Grant Disbursements

Next Steps

- Continue Reviewing Florida Cancer Innovation Fund applications, FY 2025-26
- Award FY 2025-26 Innovation Fund grants
- Monitor and evaluate program outcomes
- Disseminate project outcomes and best practices

An act relating to cancer funding; amending s. 381.915, F.S.; revising the purpose of the Casey DeSantis Cancer Research Program; revising duties of the Department of Health under the program; creating the Cancer Connect Collaborative, a council, within the department for a specified purpose; authorizing the collaborative to make certain recommendations on state policy relating to cancer research or treatment; providing for membership and meetings of the collaborative; requiring the collaborative to develop a long-range comprehensive plan for the program; requiring the collaborative to solicit input from certain stakeholders in the development of the plan; requiring the collaborative to submit the plan to the Governor and the Legislature by a specified date; specifying required components of the plan; requiring the department to provide administrative support and staff to the collaborative; requiring the collaborative to advise the department on the awarding of grants issued through the Cancer Innovation Fund; requiring the collaborative to review grant applications and make recommendations to the department for awarding grants upon the appropriation of funds to the fund; requiring the department to make the final grant allocation award; requiring the collaborative to prioritize certain applications for grant funding; revising the frequency with which the department, in conjunction with participating cancer

centers, must submit a specified report to the Cancer Control and Research Advisory Council and the collaborative; requiring the department to submit the report, and any equivalent independent reports, to the Governor and the Legislature by a specified date each year; revising requirements of such reports; beginning on a specified date, requiring that each allocation agreement issued by the department relating to certain cancer center payments include specified elements; amending s. 1004.435, F.S.; revising the membership of the Florida Cancer Control and Research Advisory Council; revising quorum requirements for council actions; providing an effective date.

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

Section 1. Present subsections (8), (9), and (10) of section 381.915, Florida Statutes, are redesignated as subsections (10), (12), and (13), new subsections (8) and (9) and subsection (11) are added to that section, and subsection (2) of that section is amended, to read:

381.915 Casey DeSantis Cancer Research Program.—

(2) The Casey DeSantis Cancer Research Program is established to enhance the quality and competitiveness of cancer care in this state, further a statewide biomedical research strategy directly responsive to the health needs of Florida's citizens, ~~and~~ capitalize on the potential educational opportunities available to its students, and promote the provision of high-quality, innovative health care for persons

undergoing cancer treatment in this state. The department shall:

(a) Make payments to cancer centers recognized by the National Cancer Institute (NCI) at the National Institutes of Health as NCI-designated cancer centers or NCI-designated comprehensive cancer centers, and cancer centers working toward achieving NCI designation. The department shall distribute funds to participating cancer centers on a quarterly basis during each fiscal year for which an appropriation is made.

(b) Make cancer innovation grant funding available through the Cancer Innovation Fund under subsection (9) to health care providers and facilities that demonstrate excellence in patient-centered cancer treatment or research.

(8) The Cancer Connect Collaborative, a council as defined in s. 20.03, is created within the department to advise the department and the Legislature on developing a holistic approach to the state's efforts to fund cancer research, cancer facilities, and treatments for cancer patients. The collaborative may make recommendations on proposed legislation, proposed rules, best practices, data collection and reporting, issuance of grant funds, and other proposals for state policy relating to cancer research or treatment.

(a) The Surgeon General shall serve as an ex officio, nonvoting member and shall serve as the chair.

(b) The collaborative shall be composed of the following voting members, to be appointed by September 1, 2024:

1. Two members appointed by the Governor, one member appointed by the President of the Senate, and one member appointed by the Speaker of the House of Representatives, based on the criteria of this subparagraph. The appointing officers

shall make their appointments prioritizing members who have the following experience or expertise:

a. The practice of a health care profession specializing in oncology clinical care or research;

b. The development of preventive and therapeutic treatments to control cancer;

c. The development of innovative research into the causes of cancer, the development of effective treatments for persons with cancer, or cures for cancer; or

d. Management-level experience with a cancer center licensed under chapter 395.

2. One member who is a resident of this state who can represent the interests of cancer patients in this state, appointed by the Governor.

(c) The terms of appointees under paragraph (b) shall be for 2 years unless otherwise specified. However, to achieve staggered terms, the initial appointees under that paragraph shall serve 3 years for their first term. These appointees may be reappointed for no more than four consecutive terms.

(d) Any vacancy occurring on the collaborative must be filled in the same manner as the original appointment. Any member who is appointed to fill a vacancy occurring because of death, resignation, or ineligibility for membership shall serve only for the unexpired term of the member’s predecessor.

(e) Members whose terms have expired may continue to serve until replaced or reappointed, but for no more than 6 months after the expiration of their terms.

(f) Members shall serve without compensation but are entitled to reimbursement for per diem and travel expenses

pursuant to s. 112.061.

(g) The collaborative shall meet as necessary, but at least quarterly, at the call of the chair. A majority of the members of the collaborative constitutes a quorum, and a meeting may not be held with less than a quorum present. In order to establish a quorum, the collaborative may conduct its meetings through teleconference or other electronic means. The affirmative vote of a majority of the members of the collaborative present is necessary for any official action by the collaborative.

(h) The collaborative shall develop a long-range comprehensive plan for the Casey DeSantis Cancer Research Program. In the development of the plan, the collaborative must solicit input from cancer centers, research institutions, biomedical education institutions, hospitals, and medical providers. The collaborative shall submit the plan to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than December 1, 2024. The plan must include, but need not be limited to, all of the following components:

1. Expansion of grant fund opportunities to include a broader pool of Florida-based cancer centers, research institutions, biomedical education institutions, hospitals, and medical providers to receive funding through the Cancer Innovation Fund.

2. An evaluation to determine metrics that focus on patient outcomes, quality of care, and efficacy of treatment.

3. A compilation of best practices relating to cancer research or treatment.

(i) The department shall provide reasonable and necessary

support staff and materials to assist the collaborative in the performance of its duties.

(9) The collaborative shall advise the department on the awarding of grants issued through the Cancer Innovation Fund. During any fiscal year for which funds are appropriated to the fund, the collaborative shall review all submitted grant applications and make recommendations to the department for awarding grants to support innovative cancer research and treatment models, including emerging research and treatment trends and promising treatments that may serve as catalysts for further research and treatments. The department shall make the final grant allocation awards. The collaborative shall give priority to applications seeking to expand the reach of innovative cancer treatment models into underserved areas of this state.

(10) Beginning July 1, 2025 ~~2017~~, and each year ~~every 3 years~~ thereafter, the department, in conjunction with participating cancer centers, shall submit a report to the Cancer Control and Research Advisory Council and the collaborative on specific metrics relating to cancer mortality and external funding for cancer-related research in this ~~the~~ state. If a cancer center does not endorse this report or produce an equivalent independent report, the cancer center is ineligible to receive ~~shall be suspended from the~~ program funding for 1 year. The department must submit this annual report, and any equivalent independent reports, to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than September 15 of each year the report or reports are submitted by the department. The report

must include:

(a) An analysis of trending age-adjusted cancer mortality rates in the state, which must include, at a minimum, overall age-adjusted mortality rates for cancer statewide and age-adjusted mortality rates by age group, geographic region, and type of cancer, which must include, at a minimum:

1. Lung cancer.

2. Pancreatic cancer.

3. Sarcoma.

4. Melanoma.

5. Leukemia and myelodysplastic syndromes.

6. Brain cancer.

7. Breast cancer.

(b) Identification of trends in overall federal funding, broken down by institutional source, for cancer-related research in the state.

(c) A list and narrative description of ~~collaborative grants and~~ interinstitutional collaboration among participating cancer centers, which may include grants received by participating cancer centers in collaboration, a comparison of such ~~collaborative~~ grants in proportion to the grant totals for each cancer center, a catalog of retreats and progress seed grants using state funds, and targets for collaboration in the future and reports on progress regarding such targets where appropriate.

(11) Beginning July 1, 2024, each allocation agreement issued by the department relating to cancer center payments under subsection (2) must include all of the following:

(a) A line-item budget narrative documenting the annual

allocation of funds to a cancer center.

(b) A cap on the annual award of 15 percent for administrative expenses.

(c) A requirement for the cancer center to submit quarterly reports of all expenditures made by the cancer center with funds received through the Casey DeSantis Cancer Research Program.

(d) A provision to allow the department and other state auditing bodies to audit all financial records, supporting documents, statistical records, and any other documents pertinent to the allocation agreement.

(e) A provision requiring the annual reporting of outcome data and protocols used in achieving those outcomes.

(12) ~~(9)~~ This section is subject to annual appropriation by the Legislature.

(13) ~~(10)~~ The department may adopt rules to administer this section.

Section 2. Paragraphs (a) and (d) of subsection (4) of section 1004.435, Florida Statutes, are amended to read:

1004.435 Cancer control and research.—

(4) FLORIDA CANCER CONTROL AND RESEARCH ADVISORY COUNCIL; CREATION; COMPOSITION.—

(a) There is created within the H. Lee Moffitt Cancer Center and Research Institute, Inc., the Florida Cancer Control and Research Advisory Council. The council shall consist of 16 ~~15~~ members, which includes the chairperson, all of whom must be residents of this state. The State Surgeon General or his or her designee within the Department of Health shall be one of the 16 ~~15~~ members. Members, except those appointed by the Governor, the Speaker of the House of Representatives, or the President of the

Senate, must be appointed by the chief executive officer of the institution or organization represented, or his or her designee. One member must be a representative of the American Cancer Society; one member must be a representative of the Sylvester Comprehensive Cancer Center of the University of Miami; one member must be a representative of the University of Florida Shands Cancer Center; one member must be a representative of the Florida Nurses Association who specializes in the field of oncology and is not from an institution or organization already represented on the council; one member must be a representative of the Florida Osteopathic Medical Association who specializes in the field of oncology; one member must be a member of the Florida Medical Association who specializes in the field of oncology and who represents a cancer center not already represented on the council; one member must be a representative of the H. Lee Moffitt Cancer Center and Research Institute, Inc.; one member must be a representative of the Mayo Clinic in Jacksonville; one member must be a member of the Florida Hospital Association who specializes in the field of oncology and who represents a comprehensive cancer center not already represented on the council; one member must be a representative of the Association of Community Cancer Centers; one member must specialize in pediatric oncology research or clinical care appointed by the Governor; one member must specialize in oncology clinical care or research appointed by the President of the Senate; one member must be a current or former cancer patient or a current or former caregiver to a cancer patient appointed by the Speaker of the House of Representatives; one member must be a member of the House of Representatives

appointed by the Speaker of the House of Representatives; and one member must be a member of the Senate appointed by the President of the Senate. At least four of the members must be individuals who are minority persons as defined by s. 288.703.

(d) The council shall meet no less than semiannually at the call of the chairperson or, in his or her absence or incapacity, at the call of the State Surgeon General. Nine ~~Eight~~ members constitute a quorum for the purpose of exercising all of the powers of the council. A vote of the majority of the members present is sufficient for all actions of the council.

Section 3. This act shall take effect July 1, 2024.

a member of the collaborative or a panel from participating in certain discussions or decisions; requiring recipients of incubator grant funds to enter into an allocation agreement with the department; specifying requirements for such allocation agreements; requiring, beginning on a specified date and annually until a specified date, the collaborative to prepare and submit a specified report to the Governor and the Legislature; requiring the collaborative to make a certain recommendation under certain circumstances; requiring that a specified report include certain information; providing an effective date.

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

Section 2. Present paragraphs (c), (d), and (e) of subsection (3) and present subsections (12) and (13) of section 381.915, Florida Statutes, are redesignated as paragraphs (d), (e), and (f) of subsection (3) and subsections (13) and (14), respectively, a new paragraph (c) is added to subsection (3), paragraph (d) is added to subsection (10), a new subsection (12) is added to that section, and paragraph (b) and present paragraph (c) of subsection (3), paragraphs (a), (b), (e), (f), and (h) of subsection (8), and subsections (9) and (11) of that section are amended, to read:

381.915 Casey DeSantis Cancer Research Program.—

(3) On or before September 15 of each year, the department shall calculate an allocation fraction to be used for

distributing funds to participating cancer centers. On or before the final business day of each quarter of the state fiscal year, the department shall distribute to each participating cancer center one-fourth of that cancer center's annual allocation calculated under subsection (6). The allocation fraction for each participating cancer center is based on the cancer center's tier-designated weight under subsection (4) multiplied by each of the following allocation factors based on activities in this state: number of reportable cases, peer-review costs, and biomedical education and training. As used in this section, the term:

(b) "Cancer center" means a comprehensive center with at least one geographic site in the state, a freestanding center located in the state, a center situated within an academic institution, or a Florida-based formal research-based consortium under centralized leadership that has achieved NCI designation ~~or is prepared to achieve NCI designation by June 30, 2024~~.

(c) "Cancer Connect Collaborative" or "collaborative" means the council created under subsection (8).

(d) ~~(c)~~ "Florida-based" means that a cancer center's actual or sought designated status is or would be recognized by the NCI as primarily located in Florida and not in another state, or that a health care provider or facility is physically located in Florida and provides services in Florida.

(8) The Cancer Connect Collaborative, a council as defined in s. 20.03, is created within the department to advise the department and the Legislature on developing a holistic approach to the state's efforts to fund cancer research, cancer facilities, and treatments for cancer patients. The

collaborative may make recommendations on proposed legislation, proposed rules, best practices, data collection and reporting, issuance of grant funds, and other proposals for state policy relating to cancer research or treatment.

(a) The Surgeon General shall serve as an ex officio, nonvoting member of the collaborative and shall serve as the chair.

(b) The collaborative shall be composed of the following voting members~~, to be appointed by September 1, 2024~~:

1. Two members appointed by the Governor, three members ~~one member~~ appointed by the President of the Senate, and three members ~~one member~~ appointed by the Speaker of the House of Representatives, based on the criteria of this subparagraph. The appointing officers shall make their appointments prioritizing members who have the following experience or expertise:

a. The practice of a health care profession specializing in oncology clinical care or research;

b. The development of preventive and therapeutic treatments to control cancer;

c. The development of innovative research into the causes of cancer, the development of effective treatments for persons with cancer, or cures for cancer; or

d. Management-level experience with a cancer center licensed under chapter 395.

2. One member who is a resident of this state who can represent the interests of cancer patients in this state, appointed by the Governor.

(e) Members of the collaborative whose terms have expired may continue to serve until replaced or reappointed, but for no

more than 6 months after the expiration of their terms.

(f) Members of the collaborative shall serve without compensation but are entitled to reimbursement for per diem and travel expenses pursuant to s. 112.061.

~~(h) The collaborative shall develop a long-range comprehensive plan for the Casey DeSantis Cancer Research Program. In the development of the plan, the collaborative must solicit input from cancer centers, research institutions, biomedical education institutions, hospitals, and medical providers. The collaborative shall submit the plan to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than December 1, 2024. The plan must include, but need not be limited to, all of the following components:~~

~~1. Expansion of grant fund opportunities to include a broader pool of Florida-based cancer centers, research institutions, biomedical education institutions, hospitals, and medical providers to receive funding through the Cancer Innovation Fund.~~

~~2. An evaluation to determine metrics that focus on patient outcomes, quality of care, and efficacy of treatment.~~

~~3. A compilation of best practices relating to cancer research or treatment.~~

(9)(a) The collaborative shall advise the department on the awarding of grants issued through the Cancer Innovation Fund. During any fiscal year for which funds are appropriated to the fund, the collaborative shall review all submitted grant applications using the parameters provided in paragraph (c) and make recommendations to the department for awarding grants to

support innovative cancer research and treatment models, including emerging research and treatment trends and promising treatments that may serve as catalysts for further research and treatments. The department shall make the final grant allocation awards. The collaborative shall give priority to applications seeking to expand the reach of cancer screening efforts and innovative cancer treatment models into underserved areas of this state.

(b) To be eligible for grant funding under this subsection, a licensed or certified health care provider, facility, or entity must meet at least one of the following criteria:

1. Operates as a licensed hospital that has a minimum of 30 percent of its current cancer patients residing in rural or underserved areas.

2. Operates as a licensed health care clinic or facility that employs or contracts with at least one physician licensed under chapter 458 or chapter 459 who is board certified in oncology and that administers chemotherapy treatments for cancer.

3. Operates as a licensed facility that employs or contracts with at least one physician licensed under chapter 458 or chapter 459 who is board certified in oncology and that administers radiation therapy treatments for cancer.

4. Operates as a licensed health care clinic or facility that provides cancer screening services at no cost or a minimal cost to patients.

5. Operates as a rural hospital as defined in s. 395.602(2)(b).

6. Operates as a critical access hospital as defined in s.

408.07(14).

7. Operates as a specialty hospital as defined in s. 395.002(28)(a) which provides cancer treatment for patients from birth to 18 years of age.

8. Operates as a licensed hospital that is accredited by the American College of Surgeons as a Comprehensive Community Cancer Program or Integrated Network Cancer Program.

9. Engages in biomedical research intended to develop therapies, medical pharmaceuticals, treatment protocols, or medical procedures intended to cure cancer or improve the quality of life of cancer patients.

10. Educates or trains students, postdoctoral fellows, or licensed or certified health care practitioners in the screening, diagnosis, or treatment of cancer.

(c) To ensure that all proposals for grant funding issued through the Cancer Innovation Fund are appropriate and are evaluated fairly on the basis of scientific merit, the department shall appoint peer review panels of independent, scientifically qualified individuals to review the scientific merit of each proposal and establish its priority score. The priority scores must be forwarded to the collaborative and must be considered in determining which proposals the collaborative recommends for grant funding through the Cancer Innovation Fund.

(d) The collaborative and the peer review panels shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest regarding the assessment of Cancer Innovation Fund grant applications. A member of the collaborative or a panel may not participate in any discussion or decision of the collaborative

or a panel with respect to a research proposal by any firm, entity, or agency with which the member is associated as a member of the governing body or as an employee or with which the member has entered into a contractual arrangement.

(e) Beginning December 1, 2025, and annually thereafter, the collaborative shall prepare and submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which identifies and evaluates the performance and the impact of grants issued through the Cancer Innovation Fund on cancer treatment, research, screening, diagnosis, prevention, practitioner training, workforce education, and cancer patient survivorship. The report must include all of the following:

1. Amounts of grant funds awarded to each recipient.

2. Descriptions of each recipient's research or project which include, but need not be limited to, the following:

a. Goals or projected outcomes.

b. Population to be served.

c. Research methods or project implementation plan.

3. An assessment of grant recipients which evaluates their progress toward achieving objectives specified in each recipient's grant application.

4. Recommendations for best practices that may be implemented by health care providers in this state who diagnose, treat, and screen for cancer, based on the outcomes of projects funded through the Cancer Innovation Fund.

(10) Beginning July 1, 2025, and each year thereafter, the department, in conjunction with participating cancer centers, shall submit a report to the Cancer Control and Research

Advisory Council and the collaborative on specific metrics relating to cancer mortality and external funding for cancer-related research in this state. If a cancer center does not endorse this report or produce an equivalent independent report, the cancer center is ineligible to receive program funding for 1 year. The department must submit this annual report, and any equivalent independent reports, to the Governor, the President of the Senate, and the Speaker of the House of Representatives no later than September 15 of each year the report or reports are submitted by the department. The report must include:

(d) A description of the numbers and types of cancer cases treated annually at each participating cancer center, including reportable and nonreportable cases.

(11) Beginning July 1, 2025 ~~2024~~, each allocation agreement issued by the department relating to cancer center payments under paragraph (2)(a) ~~subsection (2)~~ must include all of the following:

(a) A line-item budget narrative documenting the annual allocation of funds to a cancer center.

(b) A cap on the annual award of 15 percent for administrative expenses.

(c) A requirement for the cancer center to submit quarterly reports of all expenditures made by the cancer center with funds received through the Casey DeSantis Cancer Research Program.

(d) A provision to allow the department and other state auditing bodies to audit all financial records, supporting documents, statistical records, and any other documents pertinent to the allocation agreement.

(e) A provision requiring the annual reporting of outcome

data and protocols used in achieving those outcomes.

(12)(a) The Legislature finds that targeted areas of cancer research require increased resources and that Florida should become a leader in promoting research opportunities for these targeted areas. Floridians should not have to leave the state to receive the most advanced cancer care and treatment. To meet this need, the Cancer Connect Collaborative Research Incubator, or "incubator" as used in this subsection, is created within the department, to be overseen by the collaborative, to provide funding for a targeted area of cancer research over a 5-year period. For the 5-year period beginning July 1, 2025, the incubator's targeted area of cancer research is pediatric cancer.

(b) Contingent upon the appropriation of funds by the Legislature, grants issued through the incubator must be awarded through a peer-reviewed, competitive process. Priority must be given to applicants that focus on enhancing both research and treatment by increasing participation in clinical trials related to the targeted area of cancer research, including all of the following:

1. Identifying strategies to increase enrollment in cancer clinical trials.

2. Supporting public and private professional education programs to raise awareness and knowledge about cancer clinical trials.

3. Providing tools for cancer patients and community-based oncologists to help identify available cancer clinical trials in this state.

4. Creating opportunities for the state's academic cancer

centers to collaborate with community-based oncologists in cancer clinical trial networks.

(c) Priority may be given to grant proposals that foster collaborations among institutions, researchers, and community practitioners to support the advancement of cures through basic or applied research, including clinical trials involving cancer patients and related networks.

(d) Applications for incubator funding may be submitted by any Florida-based specialty hospital as defined in s. 395.002(28)(a) which provides cancer treatment for patients from birth to 18 years of age. All qualified applicants must have equal access and opportunity to compete for research funding. Incubator grants must be recommended by the collaborative and awarded by the department on the basis of scientific merit, as determined by a competitively open and peer-reviewed process to ensure objectivity, consistency, and high quality.

(e) To ensure that all proposals for research funding are appropriate and are evaluated fairly on the basis of scientific merit, the department shall appoint peer review panels of independent, scientifically qualified individuals to review the scientific merit of each proposal and establish its priority score. The priority scores must be forwarded to the collaborative and must be considered in determining which proposals the collaborative recommends for funding.

(f) The collaborative and the peer review panels shall establish and follow rigorous guidelines for ethical conduct and adhere to a strict policy with regard to conflicts of interest regarding the assessment of incubator grant applications. A member of the collaborative or a panel may not participate in

any discussion or decision of the collaborative or a panel regarding a research proposal from any firm, entity, or agency with which the member is associated as a governing body member, as an employee, or through a contractual arrangement.

(g) Each recipient of incubator grant funds must enter into an allocation agreement with the department. Each such allocation agreement must include all of the following:

1. A line-item budget narrative documenting the annual allocation of funds to a recipient.

2. A cap on the annual award of 15 percent for administrative expenses.

3. A requirement for the recipient to submit quarterly reports of all expenditures made by the recipient with funds received through the incubator.

4. A provision to allow the department and other state auditing bodies to audit all financial records, supporting documents, statistical records, and any other documents pertinent to the allocation agreement.

5. A provision requiring the annual reporting of outcome data and protocols used in achieving those outcomes.

(h) Beginning December 1, 2026, and annually through December 1, 2030, the collaborative shall prepare and submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which evaluates research conducted through the incubator and provides details on outcomes and findings available through the end of the fiscal year immediately preceding each report. If the collaborative recommends that the incubator be extended beyond its 5-year lifespan, the collaborative shall make such recommendation in

the report due December 1, 2029, and shall include a recommendation for the next targeted area of cancer research. The report due on December 1, 2030, must include all of the following:

1. Details of all results of the research conducted with incubator funding which has been completed or the status of research in progress.

2. An evaluation of all research conducted with incubator funding during the 5 fiscal years preceding the report.

Section 21. This act shall take effect July 1, 2025.

Florida Cancer Innovation Fund

2024-2025 Progress Report

Florida HEALTH

Table of Contents

Executive Summary

The Casey DeSantis Cancer Research Program (section 381.915, Florida Statutes) is established to enhance the quality and competitiveness of cancer care in this state, further a statewide biomedical research strategy directly responsive to the health needs of Florida's citizens, capitalize on the potential educational opportunities available to its students, and promote the provision of high-quality, innovative health care for persons undergoing cancer treatment in this state.

Beginning December 1, 2025, and annually thereafter, the Cancer Connect Collaborative shall prepare and submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives which identifies and evaluates the performance and impact of grants issued through the Florida Cancer Innovation Fund on cancer treatment, research, screening, diagnosis, prevention, practitioner training, workforce education, and cancer patient survivorship.

A. Florida Cancer Innovation Fund Grant Awards

- In Fiscal Year 2024-25, a total of 261 applicants collectively requested more than $216 million in funding through the Florida Cancer Innovation Fund (FCIF).
- FCIF awarded $60 million for 65 groundbreaking projects statewide, driving progress in targeted therapies, early detection tools, and innovative supportive care approaches.
- The FCIF awards were distributed across 28 institutions and encompassed research on over 16 distinct cancer types.

B. Driving Progress in Cancer Care: Goals and Projected Outcomes

Across 65 funded grants, key priorities include:

- **Advancing Treatments:** Over half of the awarded projects aim to develop or refine therapies, targeting drug resistance and precision care.
- **Early Detection and Monitoring:** More than 20 awarded projects focus on better screening, biomarkers, and digital tools for timely intervention.
- **Improving Access to Care:** Over 15 awarded projects target underserved communities, working to expand screening and treatment availability and reduce barriers.
- **Immune-Based Approaches:** In addition, more than 15 awarded projects explore immunotherapy and alternatives to chemotherapy.
- **Additional innovations:** AI-guided care, gut health strategies, precision radiation, complication-reducing devices, and relapse prevention.

C. Communities in Focus: Populations Served

- Breast cancer emerged as the most frequently targeted cancer type, appearing in 42% of funded grants.
- Following breast cancer, the next most frequently addressed cancer types were lung (21.8%) and colon (18.2%) cancers.
- Twenty percent of projects concentrated on pediatric populations, aiming to address the unique needs of children with cancer.
- Nearly 5% of projects focused on addressing the distinct health care needs of older adults.
- Cancer survivors were a primary focus in 12.3% of grants, highlighting efforts to support post-treatment care and long-term health.
- In addition, 36.9% of projects prioritized improving care in rural communities.

D. Blueprint for Impact: Research Methods/Implementation Plan

- FCIF grant recipients are advancing a wide range of innovative projects that embody Florida's dedication to cutting-edge research, innovative therapies, and real-world applications.
- Initiatives span clinical tools, community-based screenings, wearable tech for survivorship, and novel therapies like microbiome-guided resistance reversal and immune-based relapse prevention.
- Translational research is pushing the boundaries of personalized care through advanced diagnostics and molecular profiling.
- Most projects are forming partnerships within 3–6 months, with implementation timelines ranging from rapid digital rollouts to longer-term therapeutic evaluations, positioning them for meaningful and scalable impact.

E. Measuring Success: Evaluating Progress

- **Scientific Readiness:** Several projects are in early execution stages, focusing on cell line development, compound synthesis, and protocol refinement to generate new data and validate therapeutic hypotheses.
- **Infrastructure Development:** Recipients are building cancer research infrastructure, including cloud platforms, imaging systems, secure databases, and genomic warehouses to support scalability and precision oncology.
- **Clinical Trials:** Clinical trials are underway with a focus on rapid patient enrollment and expedited data collection.
- **Collaborative and Regulatory Progress:** Strategic partnerships with universities, clinical networks, and tech vendors are accelerating implementation. Most grants have completed Institutional Review Board (IRB) reviews, cybersecurity assessments, and contractual agreements, ensuring high standards of safety and accountability.

F. Emerging Best Practices in Cancer Care

Recent projects that highlight key advances in precision, access, and innovation resulting from FCIF grants awarded include:

- **Clinical Precision and Therapeutic Innovation:** Projects are promoting precision oncology by developing biologically targeted treatments that reduce toxicity and improve outcomes, including exosome-blocking strategies, combination therapies for resistant cancers, and standardized tissue-based dosing protocols.
- **Patient-Centered Protocols and Workflow Flexibility:** Adaptable clinical workflows are advancing patient-centered care through tiered consent, tailored imaging, and customized procedures that enhance comfort, clarity, and responsiveness.
- **Infrastructure and Data-Driven Collaboration:** Projects are advancing shared data systems and integrated risk models to support personalized care and cross-institutional collaboration.
- **Expanding Access and Enhancing Care Delivery:** Flexible care models such as mobile units, improved infrastructure, and digital literacy support to expand rural access, ease financial burdens, and strengthen trust in community-based cancer care.
- **Recruitment and Navigation Strategies:** Teams are enhancing research participation through multi-channel recruitment and digital tools that address social needs like food security, supporting more representative and patient-aware cancer studies.

Part 1. Grant Funds Awarded to Each Recipient

- **Total Grants Awarded:** 65
- **Total Funding Allocated:** $59.87 million
- **Number of Institutions Funded:** 28

The Florida Cancer Innovation Fund (FCIF) is a strategic initiative by the state of Florida to accelerate cancer research, fuel breakthrough innovations, and improve outcomes for residents. In Fiscal Year 2024-25, FCIF awarded $60 million to 65 pioneering projects across the state, supporting advancements in targeted therapies, early detection technologies, and supportive care models. These investments reflect Florida's commitment to enhancing patient outcomes, expanding access to advanced care, and improving quality of life for individuals and families affected by cancer.

This report highlights the impact of FCIF's funding on scientific discovery, clinical innovation, and real-world benefits for Floridians. By supporting projects that integrate multidisciplinary collaboration, AI-powered tools, and patient-centered approaches, FCIF is moving Florida forward as a national leader in cancer care. These funded initiatives address urgent challenges such as treatment resistance, pediatric oncology support, and chronic symptom management that will ultimately work to reduce mortality, lower health care costs, and strengthen the state's research infrastructure.

Collectively, the FCIF awards for FY 2024-25 exemplify a balanced portfolio that drives research forward while delivering immediate and enduring benefits to Florida's citizens. In terms of research, the funds support multidisciplinary teams, preclinical validations, and data-driven insights, fostering an ecosystem of innovation that attracts talent and federal grants. Innovations like nanoparticle platforms, supportive networks, and AI diagnostics not only address specific cancers but also create adaptable models for broader application, promoting open science and knowledge sharing.

The FCIF awarded 65 grants to 28 institutions statewide. Key points about the awardees are summarized below and information for each is presented in Table 1.

- Leading recipients included the University of South Florida, H. Lee Moffitt Cancer Center, and the University of Florida, each securing multiple grants and multi-million-dollar funding.
- While academic institutions dominated in volume, several private companies and nonprofit organizations (e.g., First Ascent Biomedical and Live Like Bella Foundation) received high-value individual awards, reflecting the program's commitment to innovation and diversification.
- Projects ranged from large-scale research initiatives to targeted clinical applications, with funding levels tailored to scope and impact. This broad distribution underscores Florida's strategic investment in advancing cancer care through collaboration, infrastructure, and translational science.

Table 1: Awards by Institution, Sum of Grants per Institution, Total Funding per Institution

Institution	Sum of Grants	Sum of Budget
University of South Florida	6	$7,223,367.00
H. Lee Moffitt Cancer Center & Research Institute, Inc.	5	$6,175,958.00
University of Florida	6	$4,343,819.00
Mayo Clinic	4	$4,326,271.50
Memorial Healthcare System	3	$4,069,676.00
University of Miami	5	$3,479,663.00
University of Central Florida	5	$3,386,730.00
Florida Cancer Specialists and Research Institute	2	$3,360,115.00
Mount Sinai Medical Center	4	$2,353,460.00
Adventist Health System/Sunbelt, Inc.	2	$2,239,362.00
First Ascent Biomedical	1	$2,000,000.00
Live Like Bella Childhood Cancer Foundation	1	$2,000,000.00
Vanquish Bio, Inc.	1	$1,996,312.00
Safeguard Surgical, Inc.	1	$1,994,665.00
Nicklaus Children's Health System	1	$1,957,615.00
Cleveland Clinic Florida	3	$1,340,188.00
Florida Institute of Technology	2	$1,022,524.00
Florida Atlantic University	3	$995,460.00
Heart of Florida Health Center, Inc.	1	$968,544.00
149 BIO, LLC	1	$941,944.00
Vigilant Laboratories	1	$882,198.00
Florida International University	1	$842,236.00
Florida State University	1	$664,966.00
Nova Southern University	1	$424,289.00
Florida A&M University	1	$281,879.00
Jupiter Medical Center, Anderson Family Cancer Institute	1	$266,766.00
Mote Marine Laboratory	1	$230,578.00
TGH Cancer Institute	1	$96,800.00
Total	**65**	**$59,865,385.50**

Most awarded grants fell into the **Standard (42.2%)** and **Pilot (37.5%)** categories, reflecting strong support for established and exploratory research models. **Consortium** grants accounted for **18.8%**, emphasizing collaborative efforts, while **post-Doc** awards made up **1.6%**.

Given the FCIF focus on innovation, it is not surprising that **Innovation** grants comprise **78.1%** of FY 2024-25 awards with a focus on advancing novel approaches in cancer research and treatment. This strong emphasis reflects Florida's commitment to accelerating the development

and clinical application of cutting-edge technologies, therapies, and care models that can significantly improve patient outcomes.

Approximately **17.2%** of the funded research focused on **best practices**, emphasizing efforts to identify, share, and implement the most effective treatment protocols across institutions. This category supports initiatives that break down silos between providers and promote consistency in high-quality care.

A smaller portion, **4.7%**, was dedicated to **data and statistics**, underscoring a critical but underrepresented area. These projects aim to improve the accessibility, timeliness, and utility of cancer-related data—an essential foundation for informed decision-making, policy development, and research collaboration (See Table 2 for a complete list of grant and research categories and research types).

Table 2: Distribution by Grant Category, Research Category and Research Type

Grant Category	Percentage of All Awarded Grants
Standard	42.2%
Pilot	37.5%
Consortium	18.8%
Post-Doc	1.6%
Research Category	
Innovation	78.1%
Best Practices	17.2%
Data Statistics	4.7%
Research Type	
Implementation	23.4%
Treatment Studies	21.9%
Translational	12.5%
Special Population	12.5%
Patient and Family Support	7.8%
Treatment-Related Morbidities	7.8%
Technology Transfer Feasibility	6.3%
Open Science	4.7%
Special Call Research	3.1%
Institutional Alignment	0.0%

Funded projects span a diverse range of research categories, with the largest share allocated to **implementation research** at **23.4%**. These projects focus on integrating proven treatments into routine care and eliminating low-value practices. **Treatment studies** received **21.9%** of funding, supporting exploration of emerging therapies and innovative care models. **Translational**

research and **special population** studies each accounted for **12.5%**, emphasizing the movement of scientific discoveries into clinical practice and addressing the needs of niche groups such as pediatric patients. This distribution reflects a strategic emphasis on practical implementation, therapeutic innovation, and translational impact, while also supporting targeted efforts in patient care, commercialization, and open collaboration.

Part 2. Disease Targets, Populations Served, and Implementation Plans

Disease Targets

Common goals for FCIF awardees include developing more effective and personalized therapies, enhancing early detection and monitoring, expanding access to care for underserved communities, and strengthening the body's natural defenses through immunotherapy and precision medicine. These efforts are supported by cutting-edge implementation strategies such as AI-powered decision tools, wearable technologies, molecular diagnostics, and translational research platforms. Each project is positioned for real-world impact and long-term scalability. The populations served reflect Florida's diverse landscape, with targeted efforts reaching children, older adults, cancer survivors, and rural communities across the state.

Among the grant recipients, 60% of projects focused on a single cancer type, while 36.9% addressed multiple types, and 3.1% address all cancers (See Table 3). In addition to these primary disease targets, many grants included specialized focus areas such as evaluating cancer in patients taking specific medications, investigating kidney damage related to treatment, and assessing stage I, II, and III cancers currently being managed at participating clinics and treatment centers.

Table 3: Number of Cancer Types Addressed as a Percentage of All Awarded Grants.

Number of Specific Cancers Addressed	Percentage Of All Awarded Grants
One cancer type	60.0%
More than one cancer type	36.9%
All cancer types	3.1%

Several projects are advancing precision medicine strategies designed to tailor cancer care through molecular profiling, targeted therapies, and personalized treatment planning. In addition to these efforts, many grants pursue bold and innovative goals, including the use of artificial intelligence to support clinical decision-making, interventions that address gut health and chronic inflammation, and the development of medical devices that minimize complications and protect organ function. Other initiatives aim to refine radiation therapy for greater accuracy and

explore new approaches to prevent cancer recurrence, ensuring that patients benefit from safer, smarter, and more effective care. Across the 65 funded grants, several key themes consistently emerged in the goals and projected outcomes:

- **Advancing Treatment Options:** More than half of the grants focus on developing new therapies or improving existing ones. These projects aim to overcome drug resistance, make treatments more precise, and repurpose existing medications to help more patients with fewer side effects.
- **Improving Early Detection and Monitoring:** Over 20 grants are working to improve early detection and real-time monitoring. This includes efforts to identify cancer earlier through better screening tools and biomarkers, use patient-reported symptoms and digital platforms to flag concerns sooner, and improve outcomes by enabling timely intervention.
- **Expanding Access and Reducing Gaps in Care:** Over 15 grants are focused on reaching underserved communities across Florida. These efforts aim to expand access to screening and treatment, reduce barriers to care, and ensure that lifesaving services are available to everyone, regardless of location or background.
- **Enhancing the Body's Natural Defenses:** Over 15 grants are exploring ways to strengthen the immune system and reduce reliance on harsh chemotherapy. These projects include immunotherapy innovations and strategies to make cancer care safer, more personalized, and more effective.

Population Served

FCIF awardees target the cancers that impact the highest numbers of Floridians, including, breast, lung, and colon cancers and highlight the urgent need for improved diagnostics and treatment in these areas. Beyond disease focus, the grants demonstrate a commitment to reaching often underserved populations. Numerous initiatives are thoughtfully tailored to support pediatric patients, older adults, and cancer survivors, ensuring that innovative care solutions span all age groups and phases of survivorship. A significant number of grants also prioritize rural communities, where access to specialized cancer care can be limited. By tailoring research and implementation strategies to the needs of these populations, the program aims to reduce gaps in patient care, improve outcomes, and deliver meaningful impact statewide.

Across the funded projects, breast cancer was the most frequently targeted, appearing in 41.8% of grants. Lung cancer followed at 21.8%, with colon cancer addressed in 18.2% of awards (See Table 4 for a complete list of cancer types). These three cancer types represent a significant portion of Florida's cancer burden and were prioritized for their high prevalence, mortality rates, and potential for improved outcomes through early detection and innovative treatment. Breast cancer initiatives included personalized therapies, community-based screening, and survivorship care. Lung cancer projects explored immunotherapy, digital symptom tracking, and interventions for patients with complex health profiles. Colon cancer research focused on precision diagnostics, inflammation-related progression, and strategies to enhance staging and

treatment planning. By concentrating resources on these high-impact areas, the FCIF is accelerating progress where it is most urgently needed.

Table 4: Leading Cancer Type in Awarded Studies

Cancer Type	Percentage of All Awarded Grants
Breast	41.8%
Lung	21.8%
Colon	18.2%
Gynecological	16.4%
Prostate	14.5%
Brain	12.7%
Skin	7.3%
Pancreas	7.3%
Musculoskeletal	3.6%
Bladder	3.6%
Liver	3.6%
Throat	3.6%
Blood	1.8%
Stomach	1.8%
Non-Hodgkins Lymphoma	1.8%
Testicular	1.8%

Importantly, 36.9% of grants prioritized rural populations, where geographic isolation, provider shortages, and transportation barriers often limit access to timely and effective cancer care (See Table 5). These projects are working to expand screening programs, deploy mobile health units, integrate telemedicine, and build community partnerships to ensure that rural residents receive equitable support throughout their cancer journey.

In addition to targeting specific cancer types, the FCIF grants reflect a deep commitment to serving populations that are often underrepresented or face unique challenges in accessing quality cancer care. Twenty percent of the funded projects focused on pediatric populations, supporting research that addresses the distinct biological, developmental, and psychosocial needs of children and adolescents with cancer. These initiatives include efforts to reduce long-term treatment toxicity, improve survivorship outcomes, and develop therapies tailored to pediatric tumor biology.

Cancer survivors were also a key focus, with 12.3% of grants addressing the long-term needs of individuals who have completed initial treatment. These efforts include monitoring for

recurrence, managing chronic side effects, and supporting emotional and physical recovery through survivorship care plans and digital health tools.

A smaller but critical portion of grants (4.6%) centered on geriatric populations, recognizing the complexities of treating older adults who may have multiple comorbidities, reduced physiological resilience, and limited access to specialized care. These projects aim to optimize treatment regimens for older patients, minimize adverse effects, and improve quality of life through age-sensitive approaches. Together, these targeted efforts underscore the program's dedication to deliver transformative cancer care to every corner of Florida.

Table 5: Key Populations Benefiting from Research Initiatives

Populations Served	Percentage of All Awarded Grants
Rural	36.9%
Pediatric	20.0%
Survivors	12.3%
Geriatric	4.6%

Implementation Plan

The FCIF grant recipients are leading a bold and multifaceted wave of cancer research and implementation efforts that reflect the state's commitment to scientific advancement and practical impact. These initiatives span a wide range of technologies, therapeutic strategies, and clinical applications, each designed to accelerate progress in cancer care and improve outcomes for patients across Florida. From digital innovation to molecular diagnostics, the projects are positioned for rapid deployment and long-term scalability.

Building on this momentum, the FCIF's collection of initiatives is strategically organized around several key domains that reflect both the breadth and depth of the funded efforts. These focus areas highlight the integration of cutting-edge science with practical delivery models, ensuring that innovation is not only pursued in the lab but translated into meaningful improvements in patient care. From digital platforms that empower clinicians and survivors to therapeutic breakthroughs and scalable partnerships, each category underscores the FCIF's commitment to accelerating impact across the cancer care continuum.

Key Areas of Focus

- **Digital and Clinical Tools Projects** include artificial intelligence-powered decision support systems, integrated symptom monitoring within electronic health records, and wearable technologies that enhance survivorship care and patient engagement.

- **Therapeutic Innovation Studies** are exploring novel approaches such as microbiome-guided resistance reversal, immune-based relapse prevention, and antibody engineering to protect vital organs during treatment.
- **Translational Research:** Several grants are advancing personalized care through cutting-edge techniques like spatial lipidomics, cellular pathomics, and the development of diagnostic assays that improve early detection and treatment precision.
- **Implementation and Partnerships Collaborations** are being established or expected within three to six months, with implementation timelines ranging from under 3 months for digital tools to 6 to 12 months or more for therapeutic efficacy reporting. These timelines ensure each project is primed for real-world impact and scalable adoption.

Part 3. Achieving Objectives

FCIF is catalyzing a diverse portfolio of research initiatives that spans early discovery, infrastructure development, and translational application. Across the funded grants, the following three dominant themes emerge, each reinforcing the state's commitment to advancing cancer care through strategic, evidence-based innovation.

- **Early Experimental Launch and Scientific Readiness:** Several grant recipients are in the initial stages of execution, focusing on cell line development, compound synthesis, and protocol refinement. These foundational efforts are essential for generating new data and validating hypotheses that will inform future therapies. Investigators are actively resolving logistical challenges, acquiring specialized materials, and preparing for trial accrual, which demonstrates strong momentum and scientific discipline.
- **Infrastructure Building and Data Integration:** A significant portion of grant recipients are dedicated to strengthening Florida's cancer research infrastructure. This includes cloud-based data platforms, imaging technologies, secure databases, and genomic warehouses. These investments support long-term scalability, interoperability, and regulatory compliance, helping Florida maintain its leadership in precision oncology and data-driven public health.
- **Strategic Collaborations and Regulatory Alignment:** Grant recipients are leveraging partnerships with universities, clinical networks, and technology vendors to accelerate progress. Nearly all grants have engaged in IRB processes, cybersecurity reviews, and contractual agreements, which reflects a high level of regulatory stewardship. These collaborations are advancing technical capabilities while ensuring that taxpayer-funded research meets the highest standards of safety, transparency, and accountability.

Part 4. Best Practice Recommendations

From cutting-edge treatments to smarter ways of reaching patients, FCIF projects are pushing cancer care toward a future that's more precise, more accessible, and more innovative. These initiatives are designed to improve cancer care through a range of emerging best practices, including digital tools that enhance food security, flexible care models for rural access, and

multimodal recruitment strategies for personalized care decisions. Anticipated innovations include exosome-blocking therapies for breast cancer, combination treatments for drug-resistant triple-negative breast cancer, and personalized lung cancer risk models that integrate clinical, genetic, and behavioral data. Additional efforts focus on refining clinical workflows, expanding diagnostic options, and building collaborative data repositories to guide more effective, patient-centered care across Florida and beyond.

The FCIF is driving transformative change across the cancer care continuum, with initiatives that expand access, modernize research practices, and advance precision therapeutics and imaging. Examples include:

- **Bringing Care Closer: Mobile Models and Digital Tools for Broader Access**
  Improving access to care is another key theme, with strategies such as:
  - Mobile and home-based care delivery for rural patients.
  - Digital tools that support nutrition and remote engagement.
  - Flexible models that allow earlier patient involvement.
  - Saliva-based testing is gaining attention as a promising method for broader disease screening.
- **From Outreach to Outcomes: Building Better Cancer Studies**
  Research and recruitment practices are evolving to be more efficient and representative.
  - Multi-modal outreach, tiered consent processes, and dynamic eligibility criteria help reduce barriers and improve study quality.
  - Early implementation feedback is being used to refine protocols and guide future efforts.
- **Targeted Progress: New Therapeutics and Tailored Imaging for Better Outcomes**
  Innovative therapeutics and procedural refinements are also central to progress.
  - Exosome-blocking strategies to prevent recurrence.
  - Imaging protocols are being adjusted to better suit patient needs, supporting more responsive and individualized care.

Together, these efforts reflect a bold and collaborative push to transform cancer care in Florida, making it more precise, welcoming, and responsive to patient needs. From groundbreaking therapies to smarter research practices and expanded access, the momentum is unmistakable. As these innovations continue to evolve, they hold the promise of not only improving outcomes but also reshaping the experience of care for patients and families across the state.

Table 6. Best Practice Recommendation

Theme	Best Practice	Description
Clinical Precision and Therapeutic Innovation	Block cancer-promoting exosomes	A future adjuvant strategy to prevent recurrence and reduce reliance on chemo/hormone therapy.
	Combine chemo and immune therapy	Selectively targets cancer cells and genes in drug-resistant triple-negative breast cancer.
	Standardize tissue characterization for ion-radiation	Establishes preferred method for calculating relative biological effectiveness in radiation therapy.
Patient-Centered Protocols and Workflow Flexibility	Use tiered consent and imaging alternatives	Enables inclusive engagement and substitutes DEXA with radiological imaging for cachexia/pancreatic care.
	Disable automated CT scanner prompts	Improves patient comfort by removing unnecessary breath-hold instructions.
Infrastructure and Data-Driven Collaboration	Build multimodal lung cancer risk models	Integrates clinical, genetic, imaging, and behavioral data for personalized care pathways.
	Create collaborative health care data repositories	Facilitates knowledge exchange and real-world best practice identification across institutions.
Access Expansion and Focused Delivery	Deploy mobile units and flexible care models	Expands access in rural areas, improves satisfaction, and reduces financial stress.
Recruitment and Navigation Strategies	Use multi-modal recruitment methods	Enhances sample diversity and efficiency through varied outreach strategies.
	Develop digital tools for food security support	Connects cancer patients to nutrition resources to improve diet quality and care outcomes.
	Incorporate Breast CT into screening and diagnostics	Enhances imaging precision and streamlines breast cancer diagnostic workflows.

Appendix 1: FY 2024-25 Awardees

CASEY DESANTIS CANCER RESEARCH PROGRAM

Florida Cancer Innovation Fund Awardee

Fiscal Year 2024-25, Round 1

Institution	Principal Investigator	Budget Requested	Title of Project	Cancer Type	Research Type
University of Florida	Christina von Roemeling	$924,371.00	Fueling Immunity: Targeting Lipid Metabolism to Enhance Immune Checkpoint Blockade and Brain Metastasis Control in Triple-Negative Breast Cancer	Breast Cancer	Translational
University of Florida	Dejana Braithwaite	$598,993.00	Florida Partnership for Adding Social Context to Address Cancer Survivorship Outcomes (ASCENT)	Colon, Gynecologic	Implementation
University of South Florida	Timothy Yeatman	$1,995,456.00	Integrating spatial analysis of the lipidome, transcriptome, and microbiome to fundamentally advance our understanding of the tumor microenvironment at the single cell level---a key to cancer cures	Colon, Endometrial	Translational
SafeGuard Surgical, Inc.	Scott Kelley	$1,994,665.00	Developing a biodegradable stent to protect patients from post-surgical anastomotic leaks (AL) following rectal cancer surgery	Colon Cancer	Treatment-Related Morbidities
Moffitt Cancer Center	Derek Duckett	$1,754,880.00	Reprogramming Cancer: A Paradigm Shift in Oncology Treatment	Breast Cancer	Treatment Studies
University of Miami	Harleen Kaur	$328,052.00	Effects of a multimodal exercise intervention on chemotherapy uptake in newly diagnosed pediatric and AYA sarcoma patients	Pediatric And AYA Sarcoma	Special populations
University of Miami	Tracy Crane	$557,637.00	Fasting InTervention for Endometrial cancer (FIT-ENDO)	Endometrial	Open Science
University of South Florida	Laura Szalacha	$309,993.00	Increasing Lung Cancer Screening Uptake by Innovatively Using TIMS©, a Tailored Navigation Intervention, among Underserved Populations	Lung Cancer	Special populations
University of South Florida	Victoria Marshall	$213,219.00	GOALHealth: Geriatric Oncology Adherence Link: Testing an Established Prototype to Support Older Adults Prescribed Oral Anticancer Medication	Non-Specific	Special populations
University of Central Florida	Annette Khaled	$257,948.00	Exosome Interception: A New Strategy to Stop Breast Cancer Metastasis	Breast Cancer	Treatment Studies

University of Central Florida	Jihe Zhao	$510,656.00	Make FDA-Approved Anticancer Drugs Effective for the Most Difficult-to-Treat Breast Cancer Patients by Targeting a Novel Drug-Resistant Cancer Gene Using Innovative Drug-Delivery Technologies	Breast Cancer	Treatment Studies
University of Florida	Paul Okunieff	$1,592,243.00	Complementary Utility of Two HPV Biomarkers to Optimize Response and Personalize Cervical Cancer Treatment	Cervical Cancer	Translational
Florida State University	Michael Gubanov	$664,966.00	CancerAIKG: a Web-scale Trustworthy AI-Knowledge Graph-LLM hybrid on Cancer, Constructed and Interrogated for Bias using Deep-Learning	Breast, Colon, Small Cell Bladder	Technology Transfer Feasibility
Florida Institute of Technology	Nezamoddin Kachouie	$422,453.00	A Multimodal Lung Cancer Risk Assessment Model using Comprehensive Data Integration	Lung Cancer	Implementation
149 BIO, LLC	Darlah Lopez	$941,944.00	Mitigation of Chemotherapy-induced Nephrotoxicity via Podocyte Protection	Kidney Damage Associated with Cancer Treatment	Translational
First Ascent Biomedical	Noah Berlow	$2,000,000.00	Reducing Cancer Health Disparities in Florida through Functional Precision Medicine and Artificial Intelligence - Pilot Study serving Minority, Underserved Cancer Patients.	Precision Medicine (Including for Pediatrics)	Special populations
Moffitt Cancer Center	Hyo Han	$1,429,728.00	A Chemotherapy-free Treatment Regimen for HER-2 Positive Breast Cancer utilizing HER2-directed Intratumoral Dendritic Cell Immunotherapy plus Trastuzumab and Pertuzumab	Breast Cancer	Treatment Studies
Moffitt Cancer Center	Heather Jim	$1,561,399.00	Patient-Reported Outcomes as Novel Biomarkers for Monitoring Cancer Progression and Response to Treatment: A Validation Study	Lung, Breast	Treatment-Related Morbidities
University of Miami	Nagaraj Nagathihalli	$1,410,132.00	Urolithin A (UroA), a natural compound, as a novel therapy to reduce chemotherapy-induced toxicity in pancreatic cancer patients	Pancreatic Cancer	Treatment Studies
Mayo Clinic Jacksonville	Chris Beltran	$946,965.00	Advancing Personalized Ion Radiation Therapy: Integrating Cellular Pathomics and Relative Biological Effectiveness Modeling for Improved Cancer Outcomes in Florida.	Pancreatic, Brain	Implementation

Mayo Clinic Florida	Sungjune Kim	$781,795.00	Epigenetic Immune Regulation in Breast Cancer	Breast Cancer	Translational
Mayo Clinic Jacksonville	John Copland	$730,227.50	Induction of catabolism as a therapeutic strategy to enhance sensitivity to the SCD1 blockade therapy in hepatobiliary cancers	Liver Cancer	Translational
University of Central Florida	Claudia Andl	$380,272.00	Characterization of probiotic Lactobacillus spp. and their metabolites as a novel therapeutic for esophageal adenocarcinoma in innovative pre-clinical model systems	Esophageal Adenocarcinoma	Treatment Studies
Memorial Healthcare System	Atif Hussein	$1,280,557.00	AI-Enhanced Biomarker-Driven Early Detection and Precision Therapies for Glioblastoma and Brain Metastasis	Glioblastoma/Breast Cancer Brain Metastases	Translational
Florida A&M	Mandip Sachdeva	$281,879.00	Development of Genetically Engineered Smart Exosomes for Targeted Treatment of Cancer	Breast, Pediatric	Technology Transfer Feasibility
Nova Southeastern University	Dmitriy Minond	$424,289.00	Pre-clinical studies of splicecosomal immunomodulators in combination with checkpoint inhibitors in humanized melanoma mouse model.	Skin Cancer	Treatment Studies
Mount Sinai Medical Center	Oleg Gligich	$156,300.00	A Retrospective Review and Cross-Platform Comparison of ctDNA Results for Standardization, Clinical Validation, and Application in Cancer Monitoring.	Lung, Breast, Colon, Prostate, Bladder	Implementation
Florida Institute of Technology	Nezamoddin Kachouie	$600,071.00	A Twin SQL and Smart Cancer Repository and Query System with Analytical Intelligence Capability and Shared Access	Lung Cancer	Open Science
Vigilant Laboratories	Elizabeth Franzmann	$882,198.00	Rapid, low-cost early detection test for lung cancer	Lung Cancer	Technology Transfer Feasibility
Adventist Health System/Sunbelt, Inc.	Mark Socinski	$1,703,501.00	Building on Trust: Navigating Preventive Lung, Breast, and Prostate Cancer Screenings at Community Resource Spots	Lung, Breast, Prostate	Implementation

CASEY DESANTIS CANCER RESEARCH PROGRAM

Florida Cancer Innovation Fund Awardees

Fiscal Year 2024-25, Round 2

Institution	Principal Investigator	Budget Requested	Project Title	Cancer Type	Research Type
Heart of Florida Health Center, Inc.	Nicholas Dorsey	$968,544.00	Heart of Florida Health Center, Cancer Screening and Access to Care Project (CSACP)	Breast, Colon, Skin, Other Specify (Cervical Cancer)	Special Populations
Mount Sinai Medical Center	Steven Hochwald	$1,467,160.00	Utilizing navigation and education to improve NCCN guideline-driven care quality for patients with gastric and gastroesophageal (GEJ) junction malignancy in regions of Florida.	Other Specify (Gastric and gastroesophageal junction cancer)	Implementation
University of Central Florida	Michael Rovito	$238,919.00	Feasibility of the Physical Activity and Connectivity for Testicular Cancer Survivors (PACT) program	Other Specify (testicular)	Implementation
Cleveland Clinic Florida	Diego Sadler	$625,822.00	Cardio-Oncology Consortium to evaluate and improve the cardiovascular care of cancer patients in Florida utilizing the Global CardioOncology Registry (G-COR) platform.	Breast Cancer	Treatment-Related Morbidities
Moffitt Cancer Center	Jun Yin	$375,875.00	Novel master protocol designs for precision oncology trials in pediatric and rare cancers	Pediatric/Rare Cancers	Special Populations
University of Miami	Shanta Dhar	$506,478.00	Metabolic Modulation of Glioblastoma Stem Cells by Diet and Brain Accumulating Combinatory Nanotherapeutics for Addressing Invasion and Recurrence	Other Specify (Glioblastoma and diffuse intrinsic pontine glioma (DIPG))	Treatment Studies
University of Central Florida	Dexter Hadley	$1,998,935.00	MammoChat: An AI-Driven Platform for Personalized Breast Cancer Patient Support	Breast Cancer	Patient and Family Support
Mayo Clinic Florida	Roxana Dronca	$1,867,284.00	Cancer CARE Beyond Walls – A Pilot Clinical Trial to Evaluate Administration of Cancer Directed Therapy in the Home Versus in Clinic for Patients Residing in the Florida Panhandle and Surrounding Areas	Lung, Breast, Colon, Prostate, Skin	Special Populations

University of South Florida	Usha Menon	$729,391.00	Promoting HPV Self-Testing in Primary Care	Other Specify (cervical cancer)	Implementation
Florida Cancer Specialists and Research Institute	David Wenk	$2,000,000.00	Scaling Remote Temperature Monitoring in Community Oncology: Establishing a New Standard of Care for Early Infection Detection	Other Specify (Specific cancers are not targeted in this study; all patients receiving chemotherapy at participating clinics are potentially eligible. We expect to enroll patients with all the cancers indicated in the list above.)	Implementation
Florida International University	Christian Poellabauer	$842,236.00	Digital Biomarkers of Stress Response During and After Breast Cancer Treatment	Breast Cancer	Treatment-Related Morbidities
Florida Atlantic University	Ashley Artese	$159,626.00	Exploring the feasibility of an exercise and noninvasive brain stimulation intervention in breast cancer survivors	Breast Cancer	Treatment Studies
Mount Sinai Medical Center	Stuart Kaplan	$600,000.00	Comparison of Cone Beam Breast CT with digital breast Tomosynthesis and contrastenhanced breast MRI	Breast Cancer	Implementation
TGH Cancer Institute	Gustavo Rivero	$96,800.00	Investigating the efficacy of Dexamethasone plus conventional hypomethylating agent plus BCL-2 inhibitor in the treatment of acute myelogenous leukemia (AML).	Other Specify (Acute myeloid leukemia)	Treatment Studies
Cleveland Clinic Florida	Zeina Nahleh	$142,784.00	Artificial Intelligence-Driven Support for Distress Management in Patients with Cancer	Other Specify (All types of cancer on stage I, II and III, currently undergoing treatment at Maroone Cancer Center, Cleveland Clinic Florida.)	Patient and Family Support
Cleveland Clinic Florida	Jun Zhao	$571,582.00	Targeting Lipid Signaling in Refractory and Aggressive Cancers	Other Specify (Refractory non-Hodgkin lymphoma, triple negative breast cancer, diffuse intrinsic pontine glioma)	Translational

CASEY DESANTIS CANCER RESEARCH PROGRAM

Florida Cancer Innovation Fund Awardees

Fiscal Year 2024-25, Round 2

University of Florida	Catherine Flores	$421,819.00	Developmentally regulated antigens for targeting pediatric high-grade glioma	Other Specify (Pediatric Brain Cancer)	Treatment Studies
Florida Atlantic University	Anna Knapinska	$561,276.00	MBLAC1: A Novel Target for the Treatment of Glioblastoma	Other Specify (Glioblastoma)	Treatment Studies
Florida Atlantic University	Michael Lu	$274,558.00	Targeting actin-microtubule network to enhance taxane efficacy in advanced prostate cancer	Prostate Cancer	Open Science
Vanquish Bio, Inc.	Bryan Allinson	$1,996,312.00	PANDA: Advanced AI-Driven Diagnostic Tool for Early Detection and Improved Outcomes in Pancreatic Cancer	Other Specify (Pancreas)	Technology Transfer Feasibility
Jupiter Medical Center, Anderson Family Cancer Institute	Jon DuBois	$266,766.00	Cancer Disease and Clinical Trials Education	Lung, Breast, Colon, Prostate, Other Specify (GYN Cancers)	Patient and Family Support
University of Florida	Jennifer LeLaurin	$326,326.00	Implementation of electronic patient reported outcomes for symptom management in cancer patients	Other Specify (All Cancers)	Implementation
Memorial Healthcare System	Paul Hakimata	$1,664,255.00	Maximizing Patient Inclusion In Genetic Biomarker Testing While Minimizing Time To Receive Results In Lung Cancer	Lung Cancer	Implementation
Mote Marine Laboratory	Kirstie Francis	$230,578.00	Discovery of marine natural product antagonists of Ewing Sarcoma target as novel therapies	Other Specify (Ewing Sarcoma)	Treatment Studies
Nicklaus Children's Health System	David Seo	$1,957,615.00	Advancing Precision Medicine for Pediatric Oncology with Whole Genome Sequencing (WGS) and Clinical Trials Matching	Other Specify (The type of cancer this study will address are sarcomas, such as osteosarcoma and rhabdomyosarcoma)	Special populations
Mount Sinai Medical Center	Kenneth Chu	$130,000.00	Minimizing motion in SPECTCT images of liver patients	Other Specify (Liver Cancer)	Implementation

CASEY DESANTIS CANCER RESEARCH PROGRAM

Florida Cancer Innovation Fund Awardees

Fiscal Year 2024-25, Round 3

Institution	Principal Investigator	Budget Requested	Project Title	Cancer Type	Research Type
University of South Florida	Matthew Anderson	$1,991,178.00	An AI-based platform to overcome barriers to cancer prevention in rural communities	Cervical Cancer	Implementation
University of Miami	Junwei Shi	$677,364.00	Tumor-targeted nanoplatform delivery of generic epigenetic drug for prostate cancer therapy	Prostate	Treatment Studies
University of South Florida	Pramvir Verma	$1,984,130.00	Improving Cancer Survival by Targeting Cancer Associated Bacteria with Novel Therapies.	Lung, Breast, Colon, Prostate	Technology Transfer Feasibility
Memorial Healthcare System	Ashwin Mehta	$1,124,864.00	Transforming Cancer Care in Florida: Integrative Cancer Survivorship – Synergizing Biomarkers, Clinical Trials, and Education to Prevent Recurrence and Second Cancers	Lung, Breast, Colon, Prostate, Skin, Other Specify (Liquid and Solid Tumors)	Implementation
Adventist Health System/Sunbelt, Inc.	Amanda Sawyer	$535,861.00	A Prospective Study of a Lifestyle Medicine Survivorship Program for Patients with Gynecologic Cancer	Other Specify (Gynecologic Cancer)	Patient and Family Support
Moffitt Cancer Center	Ghulam Rasool	$1,054,076.00	AI-Driven Early Detection of Cachexia in Pancreatic Cancer and Feasibility of Diet and Exercise Interventions	Pancreatic cancer	Special Call Research (Non-Pharmaceutical Intervention)
Live Like Bella Childhood Cancer Foundation	Nicole de Lara Puente	$2,000,000.00	The Live Like Bella® Comprehensive Childhood Cancer Network	Other Specify (Glioblastoma (GBM))	Patient and Family Support
University of Florida	Danielle Jake-Schoffman	$480,067.00	Leveraging Florida's Outdoor Spaces for Cancer Prevention: A Holistic Physical Activity Initiative for Cancer Survivors	All Cancer Types	Special Call Research (Non-Pharmaceutical Intervention)
Florida Cancer Specialists and Research Institute	Bradley Monk	$1,360,115.00	Bringing Cancer Research to Rural Floridians	Lung, Breast, Colon, Prostate, Skin	Patient and Family Support

Appendix 2: Research Objectives, Target Population, and Implementation Plan, *continued*

Project Title: Integrating spatial analysis of the lipidome, transcriptome, and microbiome to fundamentally advance our understanding of the tumor microenvironment at the single cell level---a key to cancer cures
Principal Investigator: Timothy Yeatman
Institution: University of South Florida
Funding: $1,995,456.00
Cancer type: Colon, Gynecologic (Endometrial)

Goals or projected outcomes

- Develop a novel, near single-cell “precision lipidomics” capability by integrating DESI-MS imaging of active lipid mediators with spatial transcriptomics on serial sections from the same tumor.
- Map, within the CRC tumor microenvironment (TME), which specific cell types produce pro-inflammatory vs. pro-resolving lipid mediators (addressing an unmet need beyond prior “bulk” tumor measurements).
- Generate deep biological insights into how dietary lipids and chronic inflammation shape the immune TME in CRC.
- Pave the way for therapeutic strategies that promote resolution of inflammation (“resolution medicine”) to improve cancer outcomes.

Population to be served

- Patients with colorectal cancer (CRC), including context highlighted in the document:
    - Rising incidence in very young patients (under 40).
    - Vulnerable rural and impoverished populations, particularly those in food deserts.
- Florida-based research focus; analyses conducted on fresh human CRC tumor tissues.

Research methods or project implementation plan

- Core technological integration
    - DESI-MS imaging: Detect and spatially resolve evanescent/active lipid mediators within tumor tissue.
    - Spatial transcriptomics: Profile cell-type–specific gene expression on serial sections from the same tumors.
    - Combined, near single-cell resolution analysis to link lipid mediator production to precise cellular identities.
- Analytical scope
    - Quantitative LC-MS/MS for active lipid mediators in fresh human CRC tumors (building on prior findings that CRCs overproduce pro-inflammatory and have few resolving mediators).
    - Joint spatial analysis of lipidome and transcriptome across the complex immune TME to determine which cell types drive pro-inflammatory vs. pro-resolving states.
    - Incorporation of microbiome context where available to understand diet/microbe–lipid–immune interactions.

Project Title: An AI-based platform to overcome barriers to cancer prevention in rural communities
Principal Investigator: Matthew Anderson
Institution: University of South Florida
Funding: $1,991,178.00
Cancer type: Gynecologic

Goals or projected outcomes

- Increase cervical cancer screening in rural communities using “point of destination” HPV self-testing integrated into busy primary care settings.
- Identify unscreened patients in real time as they present for care and navigate those with abnormal results to appropriate evaluation.
- Develop and validate AI algorithms to triage abnormal results and facilitate access to colposcopy (a service often unavailable locally).
- Pilot and refine the platform in four rural-serving clinics (where up to 95% of eligible patients appear unscreened in the past 5 years) using qualitative and quantitative feedback.
- Enable broader implementation across one of Florida’s largest safety-net health systems after successful pilot.

Population to be served

- Women eligible for cervical cancer screening in rural Florida communities.
- Patients seen in high-volume, rural-serving primary care clinics with historically low screening rates.
- Broader beneficiaries within a large Florida safety-net health system once scaled.

Research methods or project implementation plan

- Specific Aim 1: Build an AI-enhanced navigation platform to operationalize “point of destination” HPV self-testing in rural primary care; identify unscreened patients at the point of care; navigate abnormal tests to follow-up.
- Specific Aim 2: Develop AI algorithms to
    - Identify patients with abnormal results requiring colposcopy.
    - Proactively facilitate access to colposcopy despite local service gaps.
- Pilot implementation: Deploy in 4 rural-serving clinics; gather qualitative and quantitative feedback to iteratively improve algorithm performance and workflow fit.
- Project structure and readiness
    - Research category: Innovation
    - Research type: Implementation Research
    - Access to required innovative technologies/resources: Yes; partnerships expected in <3 months
    - Time to implement clinical practices once the study begins: 3–6 month

Project Title: Improving Cancer Survival by Targeting Cancer Associated Bacteria with Novel Therapies.
Principal Investigator: Pramvir Verma
Institution: University of South Florida
Funding: $1,984,130.00
Cancer type: Lung, Breast, Colon, Prostate

Goals or projected outcomes

- Identify and advance new drugs that target DnaK to restore/enhance the effectiveness of standard anti-cancer treatments.
- Generate proof-of-concept in animal studies and progress toward Phase 1 clinical trials and subsequent drug development.
- Develop a diagnostic test to identify patients who are best candidates for anti-DnaK treatment.
- Ultimately prevent cancer-associated bacteria from interfering with standard treatments, increasing cure rates and survival.

Population to be served

- Cancer patients in Florida across all ethnic groups and genders, in both rural and urban settings.
- Initial disease focus: colon, prostate, bladder, and breast cancers (using current standard-of-care regimens).
- Contextual relevance to cancers commonly treated with cisplatin and 5-fluorouracil (e.g., gastric, colorectal, pancreatic), noting higher H. pylori prevalence in rural populations.

Research methods or project implementation plan

- Build on published and patented bench research showing certain bacteria (e.g., F. nucleatum, M. hyorhinis) mediate resistance to cisplatin and 5-fluorouracil, and that this resistance can be reversed in the lab.
- Conduct animal studies to demonstrate proof-of-concept efficacy of anti-DnaK drugs in combination with standard-of-care regimens for colon, prostate, bladder, and breast cancers.
- Develop and validate a diagnostic assay to identify patients most likely to benefit from anti-DnaK therapy.
- Leverage the partnership with the University of South Florida to advance preclinical work toward Phase 1 trials and future therapeutic development.

Project Title: Promoting HPV Self-Testing in Primary Care
Principal Investigator: Usha Menon
Institution: University of South Florida
Funding: $729,391.00
Cancer type: Gynecologic (Cervical)

Goals or projected outcomes

- Evaluate feasibility, acceptability, and preliminary efficacy of HPV self-testing across four primary care clinics.
- Assess implementation aspects and quality-of-care components, including detailed analysis of both provider and patient perceptions of HPV self-test kits.
- Identify and address multilevel barriers (patient, provider, health system) to integrate HPV self-testing into routine primary care.
- Generate a scalable, sustainable implementation model leveraging a large safety-net primary care network for long-term uptake.

Population to be served

- Females aged 30–65 who are current patients in:
    - Tampa General Hospital (TGH) primary care network clinics across multiple counties,
    - The University of South Florida Family Medicine clinic, or
    - The USF College of Nursing Mobile Clinic.
- Eligibility notes in the application: no prior hysterectomy; clinics serve diverse socioeconomic environments.

Research methods or project implementation plan

- Study design and setting
    - Pilot implementation study in four primary care clinics within a large, diverse TGH network (plus USF Family Medicine and College of Nursing Mobile Clinic).
    - Focus on integrating HPV self-collection into routine clinical workflows to actively engage both providers and patients.
- Implementation evaluation
    - Feasibility: Can clinics reliably offer and process HPV self-tests within existing workflows?
    - Acceptability: Provider and patient perceptions of HPV self-testing (structured collection of attitudes, preferences, and experiences).
    - Preliminary efficacy: Early signals of effectiveness in real-world primary care (e.g., initial uptake and related outcomes as specified in the project's aims).
    - Multilevel barriers/facilitators: Systematic identification at patient, provider, and health system levels to inform scale-up.
- Project structure:
    - Grant category: Pilot Grant; Research category: Best Practices
    - The team leverages established clinical partnerships, existing protocols, and access to best practices; timeline to establish any needed agreements/partnerships is under 3 months.

Project Title: Increasing Lung Cancer Screening Uptake by Innovatively Using TIMS©, a Tailored Navigation Intervention, among Underserved Populations
Principal Investigator: Laura Szalacha
Institution: University of South Florida
Funding: $309,993.00
Cancer type: Lung

Goals and projected outcomes

- Increase lung cancer screening rates among medically underserved populations in Florida (currently only 2.4% screened).
- Reduce lung cancer mortality through earlier detection.
- Advance health by addressing disparities in access and outcomes.
- Promote smoking cessation during the screening process.
- Demonstrate feasibility and efficacy of the Tailored Intervention Messaging System (TIMS@) to boost screening uptake.

Population to be served

- Medically underserved individuals in low-income communities.
- High-risk adults aged 50–80 with a 20 pack-year smoking history (current or recent smokers).
- Rural populations facing geographic and systemic screening barriers.
- Screening-eligible residents of Southwest Florida with high tobacco use and limited care access.

Research methods and implementation plan

- Phase 1: Adaptation of TIMS@
    - Conduct 15 qualitative interviews with screening-eligible individuals.
    - Use content coding to identify screening barriers and motivators.
    - Tailor TIMS@ message library based on findings.
- Phase 2: Feasibility and Efficacy Testing
    - Randomize 40 participants:
        - Group A: Usual care (n = 20)
        - Group B: TIMS@ intervention (n = 20)
    - Measure feasibility, acceptability, and screening uptake within 3 months.
    - Apply logistic regression to assess impact.
- Intervention Components
    - Tailored messaging (web-based or in-person).
    - Patient navigation support to locate clinics and schedule screenings.

Project Title: GOALHealth: Geriatric Oncology Adherence Link: Testing an Established Prototype to Support Older Adults Prescribed Oral Anticancer Medication
Principal Investigator: Victoria Marshall
Institution: University of South Florida
Funding: $213,219.00
Cancer type: Other (Special) – Geriatric adults prescribed an oral anticancer medication

Goals or projected outcomes

- Finalize the interactive development phase of the GOALHealth web-based prototype guided by the Information-Motivation-Behavioral Skills (IMB) Model.
- Complete alpha testing to evaluate usability, content delivery (via sitemaps and UI algorithms), and age-appropriate design modifications.
- Generate comprehensive usability/engagement evidence (e.g., navigation patterns, time on screens, window transitions/revisits) and qualitative insights to refine the tool.
- Deliver a ready-for-next-phase, geriatric-tailored digital intervention to support medication and symptom management for older adults on OAAs in the home setting.

Population to be served

- Primary: Older adults (geriatric population) prescribed oral anticancer agents.
- Stakeholders informing design/evaluation: older adults, caregivers, and oncology healthcare professionals (as noted in the prototype's prior mixed-methods development).
- Florida-based implementation; special population data collection begins more than 3 months after study initiation.

Research methods or project implementation plan

- Study design: Multimethod approach to finalize the interactive prototype and conduct alpha testing.
- Guiding framework: IMB Model to structure evidence-based content and user-interface algorithms.
- User testing and analytics
    - Think-aloud, video-recorded web-interaction sessions with participants.
    - Immediate post-session focus groups (two different groups) to capture perceptions and improvement needs.
    - Back-end analytics using AWS logs to track navigation patterns, time per screen, and window transitions/revisits; log files exported for frequency/time analyses across windows.
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation
    - Special population: Geriatric Populations
    - Access to required innovative resources: Yes; agreements/partnerships in place; special-population data collection >3 months after start

Project Title: Reprogramming Cancer: A Paradigm Shift in Oncology Treatment
Principal Investigator: Derek Duckett
Institution: H. Lee Moffitt Cancer Center & Research Institute, Inc.
Funding: $1,754,880.00
Cancer type: Breast

Goals or projected outcomes

- Prevent recurrence by eliminating the capacity of DTPs to evolve into therapy-resistant tumors through DTP→adipocyte reprogramming.
- Define molecular mechanisms that control DTP-to-adipocyte fate conversion to guide therapeutic development.
- Optimize lead therapeutics identified from a high-throughput screen (>600,000 curated compounds) that control adipogenesis.
- Establish multi-omic signatures (transcriptional, proteomic, epigenetic, functional) of naïve cancer, DTP, DTEP (drug-tolerant expanded persisters), and DTP-derived adipocytes (DTP-A) to inform targeting and translation.
- Deliver preclinical evidence (in cellula/in vivo) that reprogramming DTPs reduces resistance and relapse risk.

Population to be served

- Breast cancer patients—particularly those at risk of relapse due to DTP-driven resistance.
- Disease context modeled in the application: HER2+ breast cancer.
- Florida-based beneficiaries via the lead institution (Moffitt Cancer Center) and consortium structure.

Research methods or project implementation plan

- Model generation and states
    - Generate and study four states from naïve cancer: DTP, DTEP, and DTP-derived adipocytes (DTP-A).
- Multi-omic and functional profiling (Aim 1 in HER2+ models)
    - Single-cell RNA-seq for transcriptional phenotyping.
    - Mass spectrometry–based proteomics.
    - ChIP-seq for epigenetic regulation.
    - High-content, live-cell imaging to quantify functional phenotypes.
    - Integrate these datasets to define state-specific signatures and regulatory mechanisms.
- Therapeutic discovery and optimization
    - High-throughput screening of >600k curated compounds for adipogenesis-controlling hits.
    - Medicinal/lead optimization to enhance potency and specificity for DTP→adipocyte reprogramming.
- Preclinical evaluation
    - In cellula and in vivo HER2+ breast cancer models to validate reprogramming efficacy and impact on resistance/relapse biology.
- Project structure
    - Grant Category: Consortium Grant; Research Category: Innovation.
    - Research Type: Treatment Studies.
    - Anticipated time to report treatment efficacy: More than 12 months.

Project Title: Patient-Reported Outcomes as Novel Biomarkers for Monitoring Cancer Progression and Response to Treatment: A Validation Study
Principal Investigator: Heather Jim
Institution: H. Lee Moffitt Cancer Center & Research Institute, Inc.
Funding: $1,561,399.00
Cancer type: Lung, Breast

Goals or projected outcomes

- Develop and validate an inexpensive, accurate, and reliable method to identify lung cancer progression earlier based on PROs.
- Demonstrate that specific PRO signals (e.g., insomnia as a proxy for circadian dysregulation tied to tumor burden) can flag progression weeks before scheduled imaging; pilot data cited: 77% accuracy, ~45 days before the next CT scan.
- Provide practice-changing evidence in Florida by establishing PROs as accessible biomarkers to detect changes in tumor burden between CT scans.
- Deliver algorithms ready for testing/implementation that integrate PROs for earlier progression detection, with the potential to improve outcomes.

Population to be served

- Lung cancer patients in Florida, particularly those in routine care who undergo periodic CT surveillance and can complete PRO monitoring.
- The application context emphasizes the high burden of lung cancer in Florida and targets this patient population for earlier, low-cost detection of progression.

Research methods or project implementation plan

- Study type: Validation study focused on confirming whether PROs can detect progression earlier than standard imaging.
- Approach
    - Collect PROs on a recurring cadence during routine care (including measures of insomnia/circadian disruption referenced in pilot work).
    - Apply algorithms that leverage PRO trajectories to identify patient-specific early signals of progression.
    - Compare PRO-based flags against subsequent CT scan findings to quantify accuracy, reliability, and lead time to detection.
- Analytical focus
    - Evaluate diagnostic performance (e.g., accuracy) and time advantage (days earlier than CT) relative to pilot benchmarks.
    - Use insights from mathematical modeling of patient-specific tumor dynamics and AI using multimodal datasets (as stated in the application's innovation description) to refine detection.

Project Title: A Chemotherapy-free Treatment Regimen for HER-2 Positive Breast Cancer utilizing HER2-directed Intratumoral Dendritic Cell Immunotherapy plus Trastuzumab and Pertuzumab
Principal Investigator: Hyo Han
Institution: H. Lee Moffitt Cancer Center & Research Institute, Inc.
Funding: $1,429,728.00
Cancer type: Breast

Goals or projected outcomes

- Achieve pathologic complete response (pCR) rates at surgery comparable to standard chemotherapy plus HER2 therapies, using a chemotherapy-free regimen (HER2-directed intratumoral dendritic cell immunotherapy + trastuzumab + pertuzumab).
- Reduce disseminated cancer cell burden and eliminate circulating tumor DNA (ctDNA), aiming to lower recurrence risk and improve survival with less toxicity.
- Demonstrate safety and efficacy via imaging and immune metrics, and show non-inferior (or improved) 3-year invasive disease-free survival (IDFS) compared to chemo-based standards.
- Provide a less toxic, potentially practice-changing option for eligible HER2-positive breast cancer patients.

Population to be served

- Patients with HER2-positive breast cancer, specifically:
    - HER2-enriched subtype
    - Primary tumor size 1–3 cm
    - Clinically node-negative disease
- Florida-based patients treated under this study framework.

Research methods or project implementation plan

- Design and regimen
    - Treatment: HER2-directed intratumoral dendritic cell (DC) immunotherapy combined with trastuzumab and pertuzumab.
    - Duration: 18 weeks of therapy, followed by surgery to assess response.
- Assessments and endpoints
    - Primary endpoint: Pathologic complete response (pCR) at time of surgery.
    - Secondary endpoints: 3-year invasive disease-free survival (IDFS); diminished disseminated cancer cells in bone marrow; loss of ctDNA.
    - Safety/efficacy monitoring: Breast MRI and PET imaging; quantification of tumor immune infiltration and peripheral immune response.
- Follow-up
    - Longitudinal follow-up for 3 years post-treatment to evaluate disease-free survival and durability of response.
- Project structure
    - Grant category: Standard Grant; Research category: Innovation
    - Research type: Treatment Studies
    - Anticipated timing to report treatment efficacy: More than 12 months
    - Access/partnerships: Innovative resources available; partnerships within <3 months

Project Title: AI-Driven Early Detection of Cachexia in Pancreatic Cancer and Feasibility of Diet and Exercise Interventions
Principal Investigator: Ghulam Rasool
Institution: H. Lee Moffitt Cancer Center & Research Institute, Inc.
Funding: $1,054,076.00
Cancer type: Pancreatic

Goals or projected outcomes

- Validate an AI model that detects early signs of cancer cachexia in pancreatic cancer patients using imaging, labs, and electronic records—before obvious symptoms emerge.
- Generate practical, actionable evidence on how structured diet and exercise interventions can be feasibly integrated into oncology care in Florida.
- Enable future statewide clinical trials and scalable implementation efforts based on the validated AI and feasibility findings.
- Improve survival and quality of life while reducing healthcare costs by enabling earlier identification and management of cachexia.

Population to be served

- Primary: Pancreatic cancer patients in Florida, including those represented in the multi-institutional Florida Pancreas Collaborative and prospectively enrolled patients.
- Secondary: Oncology clinicians across Florida who will provide input and benefit from insights on integrating non-pharmaceutical interventions (diet and exercise) into routine care.

Research methods or project implementation plan

- AI validation: Use multimodal clinical data (medical imaging, laboratory results, and electronic patient records) to develop and rigorously validate an early cachexia detection model.
- Data sources: Comprehensive datasets from the Florida Pancreas Collaborative plus prospectively enrolled pancreatic cancer patients in Florida.
- Feasibility assessment: Conduct structured surveys and interviews with pancreatic cancer patients and oncology clinicians across Florida to evaluate practicality, barriers, and preferences for diet and exercise programs.
- Analysis approach: Apply advanced AI techniques to survey/interview data to identify key barriers, patient preferences, and clinician insights for integrating non-pharmaceutical strategies into routine practice.

Project Title: Novel master protocol designs for precision oncology trials in pediatric and rare cancers
Principal Investigator: Jun Yin
Institution: H. Lee Moffitt Cancer Center & Research Institute, Inc.
Funding: $375,875.00
Cancer type: Other (Special topic) – Rare tumors

Goals or projected outcomes

- Develop Bayesian adaptive master-protocol designs that speed evaluation of multiple drugs across cancer subtypes while controlling false positives.
- Deliver a two-stage, three-outcome phase II basket-trial design that unifies clustering and hypothesis testing to handle treatment-effect heterogeneity.
- Create umbrella-trial methods that augment small concurrent control arms with rigorously selected prior trial/clinical-practice data to improve efficiency.
- Leverage real-world data to expedite trials and deliver safer, more effective treatments faster for pediatric and rare cancers in Florida.
- Produce simulation-validated designs and analysis workflows to guide future precision oncology trials.

Population to be served

- Pediatric cancer patients and individuals with rare tumors (special population: Pediatric Populations).
- Florida-focused impact via more efficient precision oncology trials for small, molecularly defined subgroups.

Research methods or project implementation plan

- Project Aims
    - Aim 1 (Basket trials): Two-stage, three-outcome Bayesian phase II design that integrates clustering with hypothesis testing to address heterogeneity and control error rates.
    - Aim 2 (Umbrella trials): Methods to augment limited concurrent controls using prior trial or real-world clinical data to increase power and efficiency in small populations.
- Statistical methods
    - In silico clinical trials: Extensive simulations across varied signal patterns and effect sizes to evaluate design operating characteristics (e.g., error control, power, efficiency).
    - External data leverage: Use completed randomized NCI trials in untreated AML (rare adult cancer) and Sunshine pediatric trials as reference sources for method development and validation.
- Project structure and readiness
    - Grant category: Standard Grant; Research category: Innovation.
    - Special Populations: Pediatric Populations; data collection begins immediately; outcomes tailored to this population.
    - Access to required innovative resources: Yes; partnerships/resources established in less than 3 months.

Project Title: Complementary Utility of Two HPV Biomarkers to Optimize Response and Personalize Cervical Cancer Treatment
Principal Investigator: Paul Okunieff
Institution: University of Florida
Funding: $1,592,243.00
Cancer type: Gynecologic

Goals or projected outcomes

- Use circulating HPV DNA and mRNA concentrations to track cervical cancer before, during, and after treatment to gauge real-time response.
- Investigate HPV activation by radiation and its implications for treatment response.
- Enable treatment de-intensification when appropriate (e.g., lower radiation dose, less-radical surgery, shorter chemotherapy) to reduce long-term morbidity while preserving high cure rates.
- Provide a practical, blood-based test to inform safer, more effective, and personalized care.

Population to be served

- Women with cervical cancer (HPV-associated) undergoing standard treatment.
- Florida-based implementation (investigators and infrastructure in Florida).

Research methods or project implementation plan

- Biomarkers and assays
    - Quantify HPV DNA and mRNA in biological fluids (primarily plasma) using laboratory-developed/CMS-approved methods, including branched DNA (isobDNA) technology (QuantiVirus HPV) developed and used by the team.
- Study timing and assessments
    - Serial liquid-biopsy sampling pre-, intra-, and post-therapy to measure HPV biomarker kinetics as a real-time readout of tumor response.
    - Explicitly study radiation-related HPV activation and its relationship to treatment effect (“virolysis” concept referenced from prior work).
- Decision support and personalization
    - Use biomarker trajectories to identify patients eligible for de-intensified care (reduced radiation fractionation, less-radical surgery, shortened chemotherapy) when early response is strong.
    - Maintain or escalate standard approaches when biomarker trends suggest suboptimal response.

Project Title: Fueling Immunity: Targeting Lipid Metabolism to Enhance Immune Checkpoint Blockade and Brain Metastasis Control in Triple-Negative Breast Cancer
Principal Investigator: Christina von Roemeling
Institution: University of Florida
Funding: $924,371.00
Cancer type: Breast

Goals and projected outcomes

- Investigate how dietary lipids influence the efficacy of MTI-301, an oral SCD1 inhibitor, in TNBC.
- Evaluate MTI-301 combined with anti-PD-1 immune checkpoint blockade across different fat intake conditions.
- Assess MTI-301's potential to treat brain metastases using low-intensity focused ultrasound (LIFU) for enhanced drug delivery.
- Generate translational data to support MTI-301's clinical development (Phase I trials planned for 2025).

Population to be served

- Patients with triple-negative breast cancer (TNBC), especially those with treatment-resistant disease.
- Patients with brain metastases from TNBC, facing poor prognosis and limited options.
- Underserved and rural populations in Florida, through outpatient-accessible oral therapy.

Research methods and implementation plan

- Aim 1: Dietary Lipids and MTI-301 Efficacy
  - Use TNBC PDX and syngeneic mouse models.
  - Administer high-fat or low-fat diets with MTI-301 ± anti-PD-1.
  - Analyze tumor growth, survival, immune infiltration, and lipidomic profiles.
  - Apply spatial lipidomics and cytokine profiling to study metabolic-immune interactions.
- Aim 2: MTI-301 for Brain Metastases
  - Use LIFU to transiently open the blood-brain barrier for MTI-301 and anti-PD-1 delivery.
  - Conduct pharmacokinetic studies in brain tissue and CSF.
  - Perform survival studies in intracranial TNBC models ± LIFU.
  - Profile immune responses via single-cell RNA sequencing, cytokine arrays, and 3D imaging.
- Implementation Strategy
  - Collaborative execution by University of Florida and Mayo Clinic Florida.
  - All models, equipment (including LIFU), and protocols are in place.
  - Weekly team meetings and SOPs ensure progress.
  - Designed to inform a Phase I/II clinical trial.

Project Title: Florida Partnership for Adding Social Context to Address Cancer Survivorship Outcomes (ASCENT)
Principal Investigator: Dejana Braithwaite
Institution: University of Florida
Funding: $598,993.00
Cancer types: Colon, Gynecologic

Goals or projected outcomes

- Develop and deploy a comprehensive, risk-targeted survivorship intervention that integrates PN with the MWC+ digital platform.
- Improve access to social resources and health outcomes related to diet and nutrition by addressing modifiable risk factors (e.g., food security, diet quality, digital health access).
- Use community-engaged feedback to refine the intervention and prepare for broad implementation across academic and community cancer centers.
- Assess implementation outcomes (grounded in implementation science) to optimize and scale best practices in survivorship care.

Population to be served

- Underserved cancer patients in Florida.
- Specifically includes gynecologic and colorectal cancer patients engaged for intervention adaptation and evaluation.
- Stakeholders engaged for adaptation and implementation: patients, healthcare providers, and community partners across academic and community-based settings.
- Multilingual access supported through MWC+ to address language and digital access needs.

Research methods or project implementation plan

- Design and framework
    - One-year, community-based study using qualitative and mixed methods.
    - Guided by the Socioecological Framework and community-engaged participatory methods.
- Core intervention components
    - MWC+ (EHR-based): Screens for symptoms and lifestyle risks; auto-generates referrals to social/community resources.
    - Patient Navigation: Delivers targeted support during cancer care; coordinates access to identified services.
- Adaptation and evaluation
    - Conduct interviews with patients, providers, and stakeholders to refine PN + MWC+.
    - Assess impact on modifiable risks and survivorship outcomes (e.g., resource access, nutrition).
    - Evaluate implementation to guide future scale-up.
- Project structure
    - Grant Category: Consortium Grant; Research Category: Best Practices
    - Research Type: Implementation Research.
    - Implementation timing: Indicated 3–6 months to implement clinical practices once the study begins.

Project Title: Leveraging Florida's Outdoor Spaces for Cancer Prevention: A Holistic Physical Activity Initiative for Cancer Survivors
Principal Investigator: Danielle Jake-Schoffman
Institution: University of Florida
Funding: $480,067.00
Cancer types: All

Goals or projected outcomes

- Create a sustainable "train-the-trainers" mentoring intervention among cancer survivors.
- Facilitate physical activity and social connectedness using outdoor, group cycling and supportive technology (Chainlink).
- Produce best practices and guidelines for increasing holistic wellness through social outdoor cycling.
- Investigate the intervention's impact on physical activity, social connectedness, and self-efficacy for exercise.
- Advance a highly scalable, self-sustaining model that combats social isolation and brings survivors into Florida's outdoor spaces and trail networks.

Population to be served

- Cancer survivors in Florida, particularly those engaged through citizen-led cycling clubs and participants using the Chainlink app to plan and join outdoor social bike rides.

Research methods or project implementation plan

- Mentorship model: Implement a train-the-trainers framework by partnering with cancer survivors in citizen-led cycling clubs across Florida.
- Iterative refinement and co-design: Use an iterative process with survivors to develop and refine best practices and practical guidelines for social outdoor cycling that promotes holistic wellness.
- Technology enablement: Iteratively refine the Chainlink app to meet accessibility and usability needs of participating cancer survivors and to facilitate planning, discovery, and participation in outdoor social rides.
- Evaluation focus: Investigate changes in physical activity, social connectedness, and self-efficacy for exercise attributable to the intervention.
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation; Special Call Research: Non-Pharmaceutical Interventions.
    - Access to needed innovative methods/technologies: Yes
    - Expects to establish any additional partnerships/resources in less than 3 months.

Project Title: Developmentally regulated antigens for targeting pediatric high grade glioma
Principal Investigator: Catherine Flores
Institution: University of Florida
Funding: $421,819.00
Cancer type: Brain

Goals or projected outcomes

- Increase the specificity and efficacy of adoptive cellular therapy for embryonal brain tumors—specifically brainstem gliomas (BSG) and diffuse midline gliomas (DMG).
- Identify and leverage “developmental antigens” (DevAgs)—antigens shared between developing brainstem tissue and BSG/DMG—to enable precise immunological targeting.
- Avoid the need for primary tumor resection as an antigen source and limit cross-reactivity with normal tissues by using developmentally regulated targets.
- Demonstrate antitumor efficacy using a targeted enrichment method to select specific antigens in syngeneic BSG/DMG models.

Population to be served

- Pediatric cancer patients with high-grade gliomas, particularly:
    - Brainstem glioma (BSG)
    - Diffuse midline glioma (DMG)

Research methods or project implementation plan

- Rationale and targeting strategy
    - Leverage the intersection between neural development and oncology (ontogeny-oncology links) to define developmental antigens (DevAgs) shared by developing brainstem tissue and BSG/DMG.
    - Use developing brainstem as a novel antigen source for tumors not amenable to surgical resection.
- Experimental plan
    - Identify DevAgs in BSG and DMG through comparative genomic characterization of developing neural tissue and tumors.
    - Employ a novel targeted enrichment approach to select specific DevAgs for immune targeting.
    - Apply an established adoptive cellular therapy platform that transfers tumor-reactive T cells to target DevAgs.
    - Test antitumor efficacy in syngeneic murine models of BSG and DMG; evaluate tumor killing and specificity.
- Prior platform foundation
    - The team’s adoptive T-cell platform has shown efficacy in orthotopic high-grade glioma and medulloblastoma models, providing feasibility for application to BSG/DMG.

Project Title: Implementation of electronic patient-reported outcomes for symptom management in cancer patients
Principal Investigator: Jennifer LeLaurin
Institution: University of Florida
Funding: $326,326.00
Cancer type: All

Goals or projected outcomes

- Develop, pilot, and disseminate EHR-integrated ePRO measures and tools (Epic) that incorporate the patient's voice into routine cancer care.
- Enable real-time symptom reporting and response to address problems earlier and improve evidence-based care delivery.
- Improve outcomes noted in the document (better symptom control, quality of life, and functional outcomes) while reducing emergency department visits, hospitalizations, and overall costs.
- Create shared, customizable resources that other Florida health systems can readily adopt and tailor, facilitating statewide best-practice dissemination and more empowered patient care.

Population to be served

- Cancer patients receiving treatment within participating Florida health systems adopting the Epic-integrated ePRO tools.
- Underserved populations with limited access to care (explicitly noted as experiencing delayed intervention and expected to benefit from remote ePRO monitoring).

Research methods or project implementation plan

- Platform and integration
    - Leverage the Epic EHR and patient portal to deploy ePROs using Computer Adaptive Testing (CAT) to minimize patient burden and support real-time data collection and clinical response.
    - Provide a customizable library of validated ePRO surveys and EHR tools for symptom monitoring that other systems can adopt.
- Measurement content
    - Aim 1: Build a library of 120+ questionnaire items using the NCI PRO-CTCAE Measurement System in Epic.
    - Enable patients to self-report presence, frequency, and severity across 78 cancer symptoms and treatment toxicities.
- Implementation and dissemination
    - Develop and pilot the integrated ePRO workflow within Epic, then disseminate the tools and configuration as shared resources to support best-practice uptake across Florida.
- Project structure
    - Research category: Best Practices; Research type: Implementation Research.

Project Title: Cancer CARE Beyond Walls – A Pilot Clinical Trial to Evaluate Administration of Cancer Directed Therapy in the Home Versus in Clinic for Patients Residing in the Florida Panhandle and Surrounding Are
Principal Investigator: Roxana Dronca
Institution: Mayo Clinic
Funding: $1,867,284.00
Cancer types: Lung, Breast, Colon, Prostate, Skin

Goals or projected outcomes

- Deliver high-quality cancer care at home for patients in the Florida Panhandle to reduce travel burdens, financial stress, and caregiver challenges.
- Demonstrate feasibility, safety, and patient experience of home-based cancer therapy compared to standard in-clinic treatment.
- Reduce geographic disparities through a scalable, decentralized care model that uses virtual capabilities, remote monitoring, and proactive management of complications.
- Build evidence to support broader scale-up of the Cancer Care Beyond Walls (CCBW) platform across healthcare systems.

Population to be served

- Oncology patients residing in Florida's Panhandle and surrounding rural/remote areas (underserved populations), including those requiring chemotherapy and supportive care.

Research methods or project implementation plan

- Design
    - Single-arm clinical trial evaluating feasibility, safety, and patient experience of home-based cancer therapy compared to standard in-clinic care for Panhandle residents.
- Intervention and infrastructure
    - Expand CCBW from an established operational hub at Mayo Clinic Florida to rural Panhandle communities.
    - Overnight shipping of medications and supplies directly to patients' homes.
    - Use of home-mix kits for non-hazardous drug compounding by home health nurses.
    - Remote monitoring and proactive management of treatment complications by a dedicated care team using simple technology.
- Prior feasibility (foundation for expansion)
    - Proof-of-concept launched April 2023 within a 30-mile radius of Mayo Clinic Florida, with over 250 infusions/injections administered at home without adverse events.
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation; Special population: Underserved.
    - Access to required technologies/resources: Yes; partnerships established in less than 3 months.
    - Data collection from the targeted special population: Begins more than 3 months after study initiation.

Project Title: Advancing Personalized Ion Radiation Therapy: Integrating Cellular Pathomics and Relative Biological Effectiveness Modeling for Improved Cancer Outcomes in Florida.
Principal Investigator: Chris Beltran
Institution: Mayo Clinic
Funding: $946,965.00
Cancer type: Pancreatic, Brain

Goals or projected outcomes

- Enhance precision of proton and carbon ion therapy by integrating cellular features into RBE modeling.
- Improve tumor targeting and minimize normal-tissue damage by replacing generalized tissue assumptions.
- Link nuclear morphology and chromatin organization to radiosensitivity for refined response predictions.
- Deliver a validated, cell-informed MCF MKM framework to guide treatment of complex cancers (e.g., pancreatic, brain) in Florida.

Population to be served

- Patients: Floridians with complex or treatment-resistant cancers eligible for ion therapy.
- Clinicians: Radiation oncologists and medical physicists applying personalized RBE models in treatment planning.

Research methods or project implementation plan

- Approach: Advance the Mayo Clinic Florida MCF MKM by incorporating cellular pathomics from tumor and normal cells.
- Aim 1: Characterize nuclear morphology
    - Methods: AI-assisted confocal microscopy and Coulter-based techniques.
    - Scope: Measure nuclear size and shape across tumor (e.g., pancreatic, brain) and normal (e.g., fibroblasts, epithelial) cells.
- Aim 2: Quantify DNA content and karyotype
    - Methods: High-throughput sequencing, fluorescence in situ hybridization (FISH), and cytogenomics.
    - Focus: Characterize chromatin density/organization and its role in radiation-induced damage clustering and repair.
- Aim 3: Integrate and validate within MCF MKM
    - Integration: Incorporate data from Aims 1–2 into the MCF MKM to produce refined, personalized RBE predictions.
- Project structure and readiness
    - Grant category: Standard Grant; Research category: Innovation
    - Research type: Implementation Research
    - Access to innovative technologies/resources: Yes; partnerships expected within <3 months
    - Time to implement clinical practices once the study begins: More than 6 months

Project Title: Epigenetic Immune Regulation in Breast Cancer
Principal Investigator: Sungjune Kim
Institution: Mayo Clinic
Funding: $781,795.00
Cancer type: Breast

Goals or projected outcomes

- Predict immunotherapy response: Determine whether methylation status of immune synapse genes predicts response to cancer immunotherapy, enabling selection of patients likely to benefit from upfront immunotherapy and guiding clinical decisions.
- Overcome resistance: Develop novel therapeutic strategies informed by epigenetic insights to improve existing cancer immunotherapies and design the next iteration of clinical trials.
- Mechanistic understanding: Define how epigenetic reprogramming (methylation/demethylation of promoter regions in immune checkpoint and co-stimulatory genes) contributes to immune evasion in breast cancer.
- Translational deliverables: Unravel methylation patterns of immune synapse genes to create predictive markers and identify tractable strategies to reverse resistance to immunotherapy.

Population to be served

- Breast cancer patients (breast oncology setting) who are candidates for, or receiving, cancer immunotherapy.
- Florida context: The work is Florida-based (Mayo Clinic Florida), aiming to improve outcomes for breast cancer patients in Florida through better patient selection and enhanced therapies.

Research methods or project implementation plan

- Core approach
    - Epigenetic profiling: Characterize methylation patterns of immune synapse genes (including promoters of immune checkpoint and co-stimulatory genes) in breast cancer to identify variability linked to immune evasion.
    - Mechanistic studies: Investigate how tumor–immune crosstalk drives dysregulated methylation and formation of a tumor “immunologic barrier,” clarifying tolerogenic mechanisms in the tumor microenvironment.
    - Predictive modeling: Define methylation signatures that correlate with immunotherapy response to support patient stratification.
    - Therapeutic strategy development: Use mechanistic insights to propose and refine strategies that modulate epigenetic states and improve responsiveness to existing cancer immunotherapies, informing the design of subsequent clinical trials.

Project Title: Induction of catabolism as a therapeutic strategy to enhance sensitivity to the SCD1 blockade therapy in hepatobiliary cancers
Principal Investigator: John Copland
Institution: Mayo Clinic
Funding: $730,227.50
Cancer type: Liver

Goals or projected outcomes

- Identify metabolic biomarkers predicting response to SCD1 inhibition (SSI-4) for precise patient selection.
- Demonstrate that inducing a catabolic state (e.g., fasting) enhances SSI-4 efficacy.
- Establish a biomarker-driven, metabolism-informed framework to guide SCD1-targeted therapy in liver cancers.
- Advance toward a Phase I translational study within 6–12 months, pending preclinical validation.

Population to be served

- Florida patients with hepatobiliary (liver) cancers.
- Current research in cell lines and patient-derived xenografts, with plans to translate findings to clinical care in Florida.

Research methods or project implementation plan

- Study context and rationale
  - SSI-4 targets lipid metabolism; ~50% of tested liver cancers are sensitive.
  - Sensitivity linked to catabolic metabolic states; AMPK identified as a key regulator.
- Objectives
  - Biomarkers: Define gene, protein, lipidomic, and metabolomic predictors of SSI-4 response.
  - Therapeutic Strategy: Induce/maintain catabolic states to boost SSI-4 sensitivity.
- Experimental design and models
  - Models: Liver cancer cell lines and patient-derived xenograft (PDX) models.
  - Study drug: SSI-4 (SCD1 inhibitor).
  - Biomarker discovery: Multi-omics—gene expression, protein assays, lipidomics, metabolomics.
  - Efficacy/readouts: In vitro cell proliferation assays; in vivo tumor growth (size) and survival; metabolic state characterization (catabolic vs anabolic).
- Data analysis plan
  - Group comparisons: Analysis of variance (ANOVA).
  - Associations: Regression-based correlation analyses.
  - Survival: Kaplan–Meier methods.
  - Multi-omics integration: Bioinformatic analysis across datasets to build predictive signatures.
- Project structure and readiness
  - Grant Category: Standard Grant; Research Category: Innovation.
  - Research Type: Translational Research; Phase I targeted in 6–12 months.
  - Access to required innovative technologies/resources: Yes.

Project Title: Maximizing Patient Inclusion In Genetic Biomarker Testing While Minimizing Time To Receive Results In Lung Cancer
Principal Investigator: Paul Hakimata
Institution: Memorial Healthcare System
Funding: $1,664,255.00
Cancer type: Lung

Goals or projected outcomes

- Reduce diagnostic turnaround time (TAT) by using cytology smears and liquid biopsy (LBx) instead of FFPE tissue.
- Validate the Aspyre Lung Assay (mass-parallel qPCR) for rapid, inclusive biomarker profiling.
- Correlate non-invasive results (cytology, blood, urine) with tissue-based NGS to ensure clinical accuracy.
- Integrate the workflow into clinical practice, especially for underserved and minority populations.
- Establish scalable diagnostic protocols for statewide and national adoption.

Population to be served

- All lung cancer patients, with emphasis on:
    - Underserved and minority populations in Florida.
    - Patients unable or unwilling to undergo invasive biopsies.
- Healthcare providers and systems implementing faster, more inclusive diagnostic workflows.
- Broader goal of reducing disparities in access to precision diagnostics.

Research Methods or Project Implementation Plan

- Aim 1: Implement and Validate the Aspyre Lung Assay
    - Use cytology smears and LBx (blood, urine, ccfRNA) for biomarker detection.
    - Optimize assay for sensitivity, specificity, and turnaround time.
    - Prioritize inclusivity for patients unable to undergo invasive procedures.
- Aim 2: Correlate Non-Invasive Results with Tissue-Based NGS
    - Conduct concordance study comparing cytology/LBx with FFPE-based NGS.
    - Evaluate accuracy, test failure rates, and time to results.
    - Validate non-invasive methods as clinically equivalent.
- Aim 3: Integrate Workflow into Clinical Practice
    - Establish reflex testing protocols triggered at biopsy.
    - Collaborate with community health workers and patient navigators.
    - Track metrics: TAT, testing rates, actionable variant detection.
- Implementation Strategy
    - 12-month phased timeline: equipment setup, IRB approval, recruitment, validation, analysis, dissemination.
    - Resources: Memorial Healthcare System’s molecular pathology lab, QuantStudio 5, NextSeq2000, XyAll Tissue Scraper, -80°C freezer.
    - Team: Molecular pathologists, oncologists, cytologists, technologists, data analysts.
    - Feasibility: Backed by infrastructure, partnerships, and institutional support.

Project Title: AI-Enhanced Biomarker-Driven Early Detection and Precision Therapies for Glioblastoma and Brain Metastasis
Principal Investigator: Atif Hussein
Institution: Memorial Healthcare System
Funding: $1,280,557.00
Cancer type: Brain, Breast

Goals or projected outcomes

- Significantly advance early detection and treatment of brain tumors (GBM and brain metastases) using next-generation sequencing (NGS) and liquid biopsy platforms.
- Improve sensitivity and specificity of biomarker-based diagnostics via AI-enabled prescreening, enabling earlier interventions.
- Integrate biomarker data with clinical imaging and patient history to generate actionable insights for precision oncology and optimize treatment regimens.
- Reduce mortality and improve quality of life for Florida patients with brain tumors.
- Evaluate a novel combination immunotherapy (relatlimab [anti–LAG-3] + nivolumab [anti–PD-1]) in recurrent GBM for improved safety, tolerability, and effectiveness.

Population to be served

- Florida patients with glioblastoma and brain metastases.
- Patients with recurrent GBM eligible for the proposed combination-immunotherapy clinical trial.

Research methods or project implementation plan

- Diagnostic/analytics approach
    - Apply AI tools to prescreen patients and enhance biomarker-based diagnostic performance (sensitivity/specificity).
    - Use NGS and liquid biopsy analyses with emphasis on cerebrospinal fluid (CSF) as a higher-yield biomarker source for brain tumors (not limited by the blood–brain barrier like blood).
    - Integrate biomarker outputs with clinical imaging and patient history to produce decision-support insights for precision care (earlier detection and timely responses to progression).
- Clinical trial component
    - Conduct a translational clinical trial in recurrent GBM testing relatlimab + nivolumab, assessing safety, tolerability, and effectiveness.
    - Translational phase anticipated to begin within 6 months (as indicated).
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation
    - Research type: Translational Research (phase: Other; start within 6 months)
    - Access to required innovative technologies/resources: Yes

Project Title: Transforming Cancer Care in Florida: Integrative Cancer Survivorship – Synergizing Biomarkers, Clinical Trials, and Education to Prevent Recurrence and Second Cancers
Principal Investigator: Ashwin Mehta
Institution: Memorial Healthcare System
Funding: $1,124,864.00
Cancer Type: Other (Special) – Lung, Breast, Colon, Prostate, Skin, Other solid tumors

Goals or projected outcomes

- Early detection of recurrence and second cancers in survivors of solid tumors (breast, lung, colorectal, CNS).
- Build a comprehensive, integrative survivorship care model that synthesizes AI-driven risk assessments, ctDNA biomarker monitoring/liquid biopsies, lifestyle and personalized medicine, holistic support, and early access to clinical trials for timely, effective interventions.
- Improve long-term outcomes for Florida cancer survivors and “shape the future of cancer survivorship” in the state.
- Expected impact articulated in the application: demonstrate that early detection via AI risk modeling, ctDNA monitoring, and personalized plans can reduce the incidence of recurrence and second cancers.

Population to be served

- Cancer survivors in Florida with solid tumors, specifically including breast, lung, colorectal, and CNS cancer survivors.

Research methods or project implementation plan

- Core methods
    - Evaluate AI-driven risk assessments to predict recurrence and second cancers in the above survivor groups.
    - Implement ctDNA biomarker monitoring and liquid biopsy technologies for early detection.
    - Integrate supportive, non-pharmacologic/lifestyle interventions with personalized medicine, plus early access to clinical trials.
- Project structure
    - Grant category: Pilot Grant; Research category: Innovation.
    - Partnerships/resources timeline: 3–6 months to establish necessary partnerships or access innovative resources.
    - Implementation timeline: 3–6 months to implement clinical practices once the study begins.

Project Title: Urolithin A (UroA), a natural compound, as a novel therapy to reduce chemotherapy-induced toxicity in pancreatic cancer patients
Principal Investigator: Nagaraj Nagathihalli
Institution: University of Miami
Funding: $1,410,132.00
Cancer type: Pancreatic

Goals or projected outcomes

- Restore gut barrier integrity to counteract chemotherapy-induced toxicity in pancreatic ductal adenocarcinoma.
- Reduce systemic inflammation and modulate the gut microbiome to enhance chemotherapy tolerability.
- Improve treatment adherence and survival outcomes, including reduced liver and lung metastasis.
- Elucidate mechanisms of action via activation of AHR and NRF2 signaling pathways.

Population to be served

- Pancreatic ductal adenocarcinoma patients, including high-risk subgroups such as smokers with exacerbated gut dysfunction and microbiome imbalance.

Research methods or project implementation plan

- Design and models
    - Preclinical study using genetically engineered mouse models (GEMMs), patient-derived xenografts (PDXs), and human organoid systems.
- Interventions and comparators
    - Test UroA as an adjunct to standard PDAC chemotherapy regimens: Gemcitabine + Paclitaxel and FOLFIRINOX.
- Key assessments and outcomes
    - Tumor growth by imaging and histological assessments.
    - Gut barrier integrity via permeability assays.
    - Microbiome composition via fecal sample analysis.
    - Systemic inflammation and tumor microenvironment changes.
    - Chemotherapy tolerability/adherence and survival (including liver and lung metastasis outcomes).
    - Mechanistic readouts focused on AHR and NRF2 pathway activation.
- Project structure and readiness
    - Grant category: Standard Grant; Research category: Innovation; Research type: Treatment Studies.
    - Access to required innovative technologies/resources: Yes; partnerships established in less than 3 months.
    - Anticipated timing to report treatment efficacy findings: Within 6 months.

Project Title: Tumor-targeted nanoplatform delivery of generic epigenetic drug for prostate cancer therapy
Principal Investigator: Junwei Shi
Institution: University of Miami
Funding: $677,364.00
Cancer type: Prostate

Goals or projected outcomes

- Develop and optimize a tumor-targeted, stimuli-responsive PSMA-targeted romidepsin nanoparticle (Romi-NP) to achieve tumor-specific activation and delivery.
- Demonstrate preclinical, synergistic efficacy of Romi-NP when combined with standard treatments—enzalutamide (ARSI) and radiation therapy (RT)—in both castration-sensitive (CSPC) and castration-resistant prostate cancer (CRPC).
- Elucidate mechanisms showing that romidepsin suppresses androgen receptor (AR) signaling and DNA damage repair pathways—key resistance mechanisms to ARSIs and RT.
- Improve outcomes by overcoming/delaying treatment resistance, offering a more effective and affordable option for prostate cancer patients in Florida, and providing a model for broader cancer care.

Population to be served

- Prostate cancer patients in Florida, specifically:
    - Those with CSPC and CRPC (including patients treated with ARSIs like enzalutamide and those receiving radiation therapy).

Research methods or project implementation plan

- Aim 1: Engineer and optimize a stimuli-responsive, PSMA-targeted Romi-NP to enable prostate tumor-specific delivery and activation, addressing prior limitations of free romidepsin (poor pharmacokinetics, low tumor accumulation, toxicity).
- Aim 2: Conduct preclinical studies to
    - Test therapeutic efficacy of Romi-NP in combination with enzalutamide and radiation therapy in CSPC and CRPC models.
    - Define mechanisms of action focused on suppression of AR signaling and DNA damage repair pathways (mechanisms implicated in resistance to ARSIs and RT).

Project Title: Fasting Intervention for Endometrial cancer (FIT-ENDO)
Principal Investigator: Tracy Crane
Institution: University of Miami
Funding: $557,637.00
Cancer type: Gynecologic

Goals or projected outcomes

- Establish feasibility and acceptability of a low-cost, scalable POF diet intervention versus an attention control.
- Measure the impact of POF on:
    - Pathology and clinical outcomes
    - Metabolic biomarkers (e.g., insulin, glucose, related metabolic indices as stated broadly in the application)
    - Patient-reported outcomes
- Conduct multi-omics analyses (gene and protein expression) on tumor tissue collected via the pre/post-surgery design to assess tumor-level effects of the intervention.
- Stand up the Gynecologic Oncology Research Consortium in Florida, using lessons learned to guide statewide implementation.
- Share progress and findings through an Open Science approach with quarterly updates.

Population to be served

- Women with a diagnosis of endometrial cancer who have planned surgery (hysterectomy).
- Target sample size: 42 participants

Research methods or project implementation plan

- Design: Pilot randomized controlled clinical trial (POF vs attention control) in 42 women with endometrial cancer scheduled for surgery.
- Timing and tissue collection: Pre/post-surgery design enables collection of tumor tissue to assess intervention effects on gene and protein expression at the tumor level.
- Key topics and focus areas: Endometrial cancer; time-restricted eating (prolonged overnight fasting); metabolism; metabolomics and genomics.
- Project structure and readiness
    - Grant Category: Consortium Grant (3 partners; 2 new; cross-disciplinary; partners ≥200 miles away; includes underrepresented/access-desert areas); Research Category: Innovation
    - Open Science: Yes; quarterly public/progress updates
    - Access to innovative technologies/methods/resources: Yes; partnerships in <3 months

Project Title: Metabolic Modulation of Glioblastoma Stem Cells by Diet and Brain Accumulating Combinatory Nanotherapeutics for Addressing Invasion and Recurrence
Principal Investigator: Shanta Dhar
Institution: University of Miami
Funding: $506,478.00
Cancer type: Brain

Goals or projected outcomes

- Validate that metabolic modulation leads to reduced tumorigenicity of patient-derived GSCs.
- Achieve delayed or complete inhibition of GBM recurrence using combined diet and brain-targeted nanotherapeutics (platinum-based).
- Generate data and proof-of-concept models to support a rationally designed, easily implementable therapy aimed at recurrence/resistance.
- Improve survival and establish a platform broadly adoptable by the research community.

Population to be served

- Adult and pediatric populations.
- Predominant cancers: Glioblastoma (GBM) and diffuse intrinsic pontine glioma (DIPG).

Research methods or project implementation plan

- Study design and models
    - In vitro studies on a pool of patient-derived GSCs.
    - Orthotopic patient-derived xenograft (PDX) models to test tumorigenicity and recurrence.
- Interventions/approach
    - Combined diet-based metabolic modulation with brain-accumulating combinatory nanotherapeutics (platinum-based) for targeted drug delivery to the tumor microenvironment.
- Analyses
    - Transcriptomics to verify signaling pathways and transcriptional regulators controlling metabolism and to define therapeutic implications.
- Project structure and readiness
    - Research category: Innovotion; Research type: Treatment Studies.
    - Access to innovative tools/methods: Yes; partnerships/resources establishment: >6 months.
    - Anticipated reporting of treatment efficacy: 6–12 months after study start.
    - Access to innovative tools/methods: Yes; partnerships/resources establishment: >6 months.
    - Anticipated reporting of treatment efficacy: 6–12 months after study start.

Project Title: Effects of a multimodal exercise intervention on chemotherapy uptake in newly diagnosed pediatric and AYA sarcoma patients
Principal Investigator: Harleen Kaur
Institution: University of Miami
Funding: $328,052.00
Cancer type: Other (Special) – Sarcoma

Goals or projected outcomes

- Demonstrate feasibility and acceptability of a multimodal exercise intervention during active treatment
    - Targets: consent ≥50%, adherence ≥70% completion, satisfaction ≥80% (exit surveys)
- Improve chemotherapy uptake/adherence and tolerance during treatment
- Reduce treatment-related side effects and enhance overall well-being/quality of life
- Provide evidence to support integrating personalized exercise into routine sarcoma care
- Explore biological mechanisms via biomarkers of immune function and inflammation
- Leverage innovative data-collection technologies (physical activity monitors, 3D biomechanical software, video-based research platform) to objectively track outcomes

Population to be served

- Newly diagnosed pediatric, adolescent, and young adult (AYA) patients with sarcoma undergoing active chemotherapy
- Florida-based special population (Pediatric Populations); data collection from this group begins immediately
- Conducted at/through the University of Miami, Miller School of Medicine

Research methods or project implementation plan

- Study design
    - Interventional study testing a structured, personalized, multimodal exercise program delivered during active chemotherapy
    - Feasibility/acceptability endpoints: consent rate, adherence/completion, and exit-survey satisfaction
- Outcomes and measures
    - Chemotherapy uptake/adherence and tolerance
    - Treatment-related side effects and overall well-being/quality of life
    - Mechanistic biomarkers: immune function and inflammation (pre/post comparisons as applicable)
- Data capture and tools
    - Objective monitoring with physical activity devices
    - 3D biomechanical software for movement/functional assessments
    - Novel video-based research platform to support standardized, remote, or scalable assessments
- Project structure
    - Grant category: Post-Doctoral Fellowship Grant; Research category: Innovation
    - Special Populations: Pediatric Populations (experience/partnerships indicated; outcomes tailored; immediate data collection)
    - Partnerships/resources timeline: less than 3 months to establish any needed agreements or access innovative resources

Project Title: MammoChat: An AI-Driven Platform for Personalized Breast Cancer Patient Support
Principal Investigator: Dexter Hadley
Institution: University of Central Florida
Funding: $1,998,935.00
Cancer type: Breast

Goals and projected outcomes

- Develop a secure, explainable AI platform to support breast cancer patients.
- Enhance emotional well-being, reduce isolation, and improve treatment adherence through peer engagement.
- Improve access to clinical trials via AI-guided matching using anonymized NFT-encoded data.
- Evaluate impact on emotional health, care satisfaction, and treatment engagement.
- Lay groundwork to expand MammoChat into OncoChat for broader cancer support.

Population to be served

- Breast cancer patients across Florida, especially those needing emotional support and treatment guidance.
- Patients at all stages of diagnosis and recovery, across diverse backgrounds.
- Aims to reduce disparities in access to support and clinical trials.

Research Methods and Implementation Plan

- Phase 1 (Months 1–4): Proof of Concept
    - Develop AI models using RAG and LLMs.
    - Integrate blockchain for data transparency and security.
    - Build infrastructure using AidBox (FHIR-compliant) and Google Cloud.
- Phase 2 (Months 5–8): Pilot Testing
    - Recruit pilot group (starting with 50, scaling to 20,000).
    - Analyze engagement, emotional well-being, and satisfaction.
    - Refine platform based on user feedback.
- Phase 3 (Months 9–12): Full Deployment
    - Scale to 10,000+ users.
    - Optimize AI models and community features.
    - Measure outcomes using validated tools (PRO-CTCAE, PDQ-BC, BCSC-Q, DCS).
- Key Research Components
    - AI personalization for education and peer matching.
    - Blockchain and NFTs for secure, anonymized data sharing.
    - Moderated forums with AI-enhanced community engagement.
    - Quantitative and qualitative data analysis.
- Evaluation Metrics
    - Patient-reported outcomes (anxiety, confidence, satisfaction).
    - Engagement metrics (platform use, peer interactions).
    - Clinical trial participation rates.

Project Title: Make FDA-Approved Anticancer Drugs Effective for the Most Difficult-to-Treat Breast Cancer Patients by Targeting a Novel Drug-Resistant Cancer Gene Using Innovative Drug-Delivery Technologies
Principal Investigator: Jihe Zhao
Institution: University of Central Florida
Funding: $510,656.00
Cancer type: Breast

Goals or projected outcomes

- Sensitize TNBC to existing FDA-approved therapies:
  - Restore/boost responsiveness to chemotherapy.
  - Enhance effectiveness of inhibitory immune checkpoint blocking therapy (IICBT).
- Overcome key drivers of poor outcomes linked to KLF8:
  - Reduce DNA repair–mediated drug resistance.
  - Diminish immune evasion that undermines IICBT.
  - Curb tumor spread/relapse associated with high KLF8 expression.
- Advance novel therapeutics and delivery:
  - Progress innovative KLF8-blocking drugs.
  - Establish/validate exosome-based drug delivery technologies for tumor-targeted treatment.
- Leverage cutting-edge analytics to track response and mechanisms, with the overarching aim of improving outcomes for the most difficult-to-treat breast cancer patients.

Population to be served

- Primary: Patients with triple-negative breast cancer (TNBC), particularly those with high KLF8 expression and resistance to standard therapies.
- Context: Florida-based research effort intended to benefit difficult-to-treat breast cancer patients.

Research methods or project implementation plan

- Therapeutic strategy
  - Inhibit KLF8 using newly generated KLF8-blocking drugs to counteract resistance mechanisms.
  - Combine KLF8 inhibition with FDA-approved chemotherapy and with IICBT to optimize therapeutic sensitivity.
- Delivery innovation
  - Employ innovative exosome-based delivery systems to achieve tumor-targeted administration of KLF8-blocking agents.
- Models and tools
  - Utilize novel patient-derived TNBC cell lines and mouse models (including KLF8high models) established by the team.
  - Apply cutting-edge tumor monitoring and analysis methods to assess:
    - DNA repair activity and its modulation by KLF8 inhibition.
    - Immune evasion markers and IICBT response.
    - Tumor growth, spread, and relapse dynamics.

Project Title: Characterization of probiotic Lactobacillus spp. and their metabolites as a novel therapeutic for esophageal adenocarcinoma in innovative pre-clinical model systems
Principal Investigator: Claudia Andl
Institution: University of Central Florida
Funding: $380,272.00
Cancer type: Throat

Goals or projected outcomes

- Develop and validate mouse and human organoid models to test Lactobacillus-based treatments for EAC.
- Identify and characterize anti-cancer compounds from Lactobacillus via fractionation and mass spectrometry.
- Demonstrate therapeutic effects by reducing tumor burden, suppressing carcinogenesis markers (ROS, DNA damage, inflammation), and promoting protective gene expression changes.

Population to be served

- Ultimate beneficiaries: Floridians with Barrett's esophagus (BE) and esophageal adenocarcinoma (EAC), with emphasis on rising prevalence in middle-aged (45–64) and older (51+) groups.
- Immediate study context: Preclinical mouse models and human patient-derived organoids.

Research methods or project implementation plan

- Models: Mouse EAC and 3D esophageal organoids; human organoids via collaboration.
- Interventions and product discovery
    - Test live Lactobacillus spp. and their culture-derived products.
    - Isolate and fractionate bacterial products; characterize components by mass spectrometry (with Dr. Roy).
- Evaluations: Tumor reduction, mechanistic assays (ROS, DNA damage, inflammation), and RNA-based profiling of protective signaling.
- Project structure and readiness
    - Grant Category: Standard Grant; Research Category: Innovation.
    - Research Type: Treatment Studies.
    - Anticipated timing to report treatment efficacy: 6–12 months.
    - Access to required innovative technologies/resources and partnerships: Yes (less than 3 months to establish, as indicated).

Project Title: Exosome Interception: A New Strategy to Stop Breast Cancer Metastasis
Principal Investigator: Annette Khaled
Institution: University of Central Florida
Funding: $257,948.00
Cancer type: Breast

Goals or projected outcomes

- Demonstrate that CCT (with a focus on the CCT2 subunit) controls EV biogenesis and cargo that drive breast cancer growth and metastasis.
- Test the team's peptide inhibitor (Z-TOP) to curtail the release of cancer-promoting EVs from breast cancer cells.
- Map oncogenic EV cargo regulated by CCT and show that inhibiting CCT decreases pathways/mediators of EV synthesis and tumor invasiveness.
- Advance an innovative, post-primary-treatment strategy to prevent lethal relapse by blocking cancer-supportive EVs.

Population to be served

- Ultimate beneficiaries: Floridians with breast cancer, particularly those at risk for metastatic relapse after primary treatment.
- Immediate research subjects: Preclinical breast cancer cell models used to generate and analyze EVs.

Research methods or project implementation plan

- Hypothesis/Objectives: CCT is critical for EV biogenesis that drives breast cancer progression; show CCT's control over EV content and test Z-TOP to reduce EV release.
- Study design
    - Aim 1: Evaluate CCT activity in EV biogenesis; examine EV cargo with oncogenic potential; test Z-TOP (a unique CCT inhibitor) to stop release of breast cancer EVs.
- Experimental approach
    - Manipulate CCT2 expression (depletion/overexpression) in breast cancer cells and assess effects on EV synthesis mediators and cell invasiveness.
    - Quantify EV production and characterize EV cargo linked to oncogenic signaling.
- Expected outputs:
    - Evidence that CCT regulates EV biogenesis/content and that Z-TOP suppresses pro-metastatic EV release, supporting development of a novel relapse-prevention strategy after primary therapy.
- Project structure
    - Grant Category: Standard Grant; Research Category: Innovation
    - Research Type: Treatment Studies
    - Partnerships/resources: Access to needed innovations; establishment within <3 months
    - Anticipated timing to report treatment efficacy findings: 6–12 months

Project Title: Feasibility of the Physical Activity and Connectivity for Testicular Cancer Survivors (PACT) program
Principal Investigator: Michael Rovito
Institution: University of Central Florida
Funding: $238,919.00
Cancer type: Testicular

Goals or projected outcomes

- Improve health-related quality of life (HRQoL) among testicular cancer (TCa) survivors through a tailored, low-impact physical activity (PA) program.
- Establish feasibility of implementing a structured PA program that integrates wearable technology, personalized feedback, and virtual peer support.
- Evaluate effectiveness on PA adherence and psychosocial outcomes (e.g., social connectedness), alongside HRQoL.
- Assess participant satisfaction, engagement, and perceived benefits to inform scalability.

Population to be served

- Testicular cancer survivors participating in a randomized controlled trial (target n = 50).

Research methods or project implementation plan

- Design: Randomized controlled trial with 50 TCa survivors.
- Intervention components
    - Wearable technology to support tracking and feedback
    - Personalized feedback
    - Virtual peer support to reduce access barriers (e.g., transportation, remote residence)
- Project structure and readiness
    - Grant Category: Pilot Grant; Research Category: Innovation
    - Research Type: Implementation Research
    - Anticipated time to implement clinical practices once the study begins: Less than 3 months

Project Title: Scaling Remote Temperature Monitoring in Community Oncology: Establishing a New Standard of Care for Early Infection Detection
Principal Investigator: David Wenk
Institution: Florida Cancer Specialists and Research Institute
Funding: $2,000,000.00
Cancer type: Other (Special) – All patients receiving chemotherapy at participating clinics.

Goals or projected outcomes

- Establish a scalable remote patient monitoring (RPM) program in community oncology using AION Biosystems' FDA-cleared TempShield wearable thermometer for real-time temperature tracking.
- Detect infections earlier to enable timely interventions, transforming oncology care from reactive to proactive.
- Improve patient outcomes, increase engagement/adherence, optimize care team efficiency, and reduce healthcare utilization and costs.
- Create a benchmark/new standard of care for telehealth and early infection detection in oncology.

Population to be served

- Oncology patients cared for by Florida Cancer Specialists & Research Institute (FCS) across Florida's community oncology settings (patients at elevated infection risk during cancer treatment).

Research methods or project implementation plan

- Approach and partnership
    - Implement TempShield (AION Biosystems) for continuous, remote temperature monitoring integrated with clinical workflows.
    - Use clinical decision support to generate timely alerts for abnormal readings and prompt medical action.
- Study/project structure
    - Aim 1: Design and implement a user friendly, scalable RPM system tailored to oncology patients with real time temperature monitoring and alerting; establish a telehealth benchmark.
    - Aim 2: Develop and implement strategies to increase patient engagement and adherence to the RPM program (e.g., program features and workflows to boost participation).
- Project structure and readiness
    - Grant category: Standard Grant; Research category: Innovation.
    - Research type: Implementation Research.
    - Implementation timeline: Less than 3 months once the study begins.

Project Title: Bringing Cancer Research to Rural Floridians
Principal Investigator: Bradley Monk
Institution: Florida Cancer Specialists and Research Institute
Funding: $1,360,115.00
Cancer types: Lung, Breast, Colon, Prostate, Skin

Goals or projected outcomes

- Expand clinical trial participation in rural Florida by improving patient awareness and enrollment acceptance.
- Create Florida-specific, rural-focused web-based and printed educational materials about cancer treatment trials.
- Deliver 20 educational townhall events at Florida Cancer Specialists (FCS) locations serving rural communities to increase awareness and timely trial participation.
- Pilot patient navigators at 10 rural FCS research clinics and implement a web-based clinical trial screening program to promptly engage and support interested rural patients.
- If successful, inform a potential long-term investment by FCS to sustain the approach.

Population to be served

- Rural Floridian cancer patients and survivors, particularly those served by FCS locations in rural communities.

Research methods or project implementation plan:

- Objectives and Aims
    - Objective: Leverage existing statewide clinical and research infrastructure to expand clinical trial participation in rural Florida.
        - Aim 1: Expand awareness via
            - Focus groups with rural Floridian cancer patients and survivors to identify rural-preferred learning approaches.
            - Development of Florida-specific web-based and printed educational materials focused on cancer treatment trials.
        - Aim 2: Education and outreach
            - Conduct 20 townhall educational events at FCS sites serving rural communities to increase awareness and timely participation in local FCS-run oncology trials.
        - Aim 3: Navigation and screening
            - Pilot patient navigators at 10 rural FCS research clinics offering trials.
            - Launch a web-based screening program to rapidly identify, engage, and support rural patients interested in clinical trials.

Project Title: Utilizing navigation and education to improve NCCN guideline-driven care quality for patients with gastric and gastroesophageal (GEJ) junction malignancy in regions of Florida.
Principal Investigator: Steven Hochwald
Institution: Mount Sinai Medical Center
Funding: $1,467,160.00
Cancer types: Stomach, Throat

Goals or projected outcomes

- Improve adherence to NCCN guideline–driven care for gastric and GEJ cancers.
- Reduce delays in diagnosis and treatment by providing direct navigation and education.
- Increase access to multidisciplinary specialty care, research trial therapy, supportive care, and appropriate surveillance.
- Generate best practices for a population-based, integrated care model for difficult-to-treat, lower-prevalence cancers.

Population to be served

- Patients with suspected or confirmed gastric and GEJ cancers in Florida, particularly those in high-incidence and rural areas.
- Targeted regions include:
    - South Florida: Glades, Martin, Broward, and Miami-Dade counties.
    - North/Central Florida: Putnam, Clay, Duval, Columbia, and Orange counties.
- Family members and healthcare providers who seek assistance via the project's contact points (hotlines and website/email).

Research methods or project implementation plan

- Community access points
    - Establish phone hotlines and complementary websites with email contact focused on identified high-incidence/mortality hotspots across Florida.
    - Provide points of contact for patients, families, and providers to facilitate the full care pathway.
- Navigation and guideline-based planning
    - Clinician navigators based at Mount Sinai Medical Center (MSMC) and the University of Florida (UF) will evaluate each case and identify action steps aligned with NCCN guidelines.
    - Navigation support spans diagnosis, workup, treatment planning, research options, completion of therapy/return to wellness, and surveillance.
- Project structure
    - Research category: Best Practices.
    - Large-scale community engagement effort intended to inform population-based integrated healthcare delivery.

Project Title: Comparison of Cone Beam Breast CT with digital breast Tomosynthesis and contrast-enhanced breast MRI
Principal Investigator: Stuart Kaplan
Institution: Mount Sinai Medical Center
Funding: $600,000.00
Cancer type: Breast

Goals or projected outcomes

- Validate the effectiveness of non-compression, full-3D, low-radiation Cone Beam Breast CT (CBBCT) in breast imaging workflows.
- Compare diagnostic accuracy:
    - CBBCT vs digital breast tomosynthesis (DBT) in average-risk populations.
    - Contrast-enhanced CBBCT (CE-CBBCT) vs breast MRI (bMRI) in high-risk populations.
- Evaluate patient compliance, cost-effectiveness, and operational factors related to imaging workflow.
- Catalyze a paradigm shift in breast imaging by incorporating CBBCT for the general female population (average and high risk) to reduce costs and anxiety, enhance quality of life, and improve compliance.

Population to be served

- General female population, including:
    - Average-risk women (CBBCT vs. DBT comparison).
    - High-risk women (CE-CBBCT vs. bMRI comparison).

Research methods or project implementation plan

- Imaging modality and acquisition
    - CBBCT provides isotropic 3D breast images at low radiation dose with the patient prone, no compression, ~7-second scan, full exam completed within minutes; can be performed with or without contrast.
- Comparative study design
    - Aim 1: Compare diagnostic accuracy of CBBCT vs. DBT in average-risk populations.
    - Aim 2: Compare diagnostic accuracy of CE-CBBCT vs. bMRI in high-risk populations.
    - Aim 3: Analyze patient compliance, cost-effectiveness, and related operational metrics.
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation; Research type: Implementation Research
    - Stakeholders engaged and access to established practices/data: Yes.
    - Implementation timeline once study begins: Less than 3 months.

Project Title: Minimizing motion in SPECT-CT images of liver patients
Principal Investigator: Kenneth Chu
Institution: Mount Sinai Medical Center
Funding: $130,000.00
Cancer type: Liver

Goals or projected outcomes

- Eliminate/reduce voluntary motion registration errors between CT and SPECT/PET components.
- Improve alignment/visibility of key anatomical structures (e.g., liver, bladder, kidneys) across CT and SPECT images and reduce the need for manual post-registrations.
- Demonstrate that adopting vacuum lock immobilization (common in radiation therapy) and optical surface monitoring in diagnostic imaging reduces misregistration beyond a 5 mm threshold.
- Quantify translation/rotation motion and correlate motion events with real-time monitoring alerts to support best-practice adoption in imaging workflows.

Population to be served

- Patients undergoing SPECT-CT and PET-CT imaging, with emphasis on liver patients (as per project title), within the Florida-based clinical setting described

Research methods or project implementation plan

- Intervention and tools
    - Use optical surface imaging system (OSMS) on each patient to flag movement during imaging.
    - Employ vacuum lock bags under the patient to minimize voluntary motion—translating an external beam radiation therapy immobilization practice into diagnostic radiology.
- Scope and exclusions
    - Focus on voluntary motion; involuntary motion (cardiac activity, bowel peristalsis, respiration) is not addressed in this study phase.
- Study design and sample
    - One-year evaluation including 150 patients:
        - 75 retrospective patients (no immobilization).
        - 75 prospective patients (with immobilization + OSMS).
- Project structure
    - Grant category: Pilot Grant; Research category: Best Practices.
    - Research type: Implementation Research.
    - Time to implement clinical practice(s) once the study begins: More than 6 months.

Project Title: A Retrospective Review and Cross-Platform Comparison of ctDNA Results for Standardization, Clinical Validation, and Application in Cancer Monitoring.
Principal Investigator: Oleg Gligich
Institution: Mount Sinai Medical Center
Funding: $156,300.00
Cancer types: Lung, Breast, Colon, Prostate, Bladder

Goals or projected outcomes

- Standardize ctDNA testing for routine clinical use across platforms to support consistent, personalized cancer monitoring.
- Compare ctDNA findings across three testing platforms, focusing on breast, lung, colon, and genitourinary (GU) cancers.
- Quantify accuracy, sensitivity, and reproducibility of ctDNA testing in real-world practice.
- Establish a practical, standardized approach to use ctDNA for monitoring tumor progression, detecting relapse, and evaluating treatment efficacy.
- Determine whether therapy adjustments informed by ctDNA results improve patient outcomes.
- Stated innovation: generate novel real-world ctDNA data and enable cross-platform comparisons to enhance standardization and clinical applicability.

Population to be served

- Adults with common cancers—specifically breast, lung, colon, and GU malignancies—treated in Florida whose ctDNA testing was performed in routine clinical practice.
- Setting: Florida-based care (Mount Sinai Comprehensive Cancer Center, Miami Beach). The application is not pediatric-focused.

Research methods or project implementation plan

- Study design
    - Retrospective analysis of ctDNA results collected over four years from three platforms used in clinical practice.
    - Real-world dataset spanning diverse cancer types, treatment regimens, and patient demographics.
- Analytic plan
    - Cross-platform comparison to assess concordance and identify platform discrepancies.
    - Performance evaluation of ctDNA (accuracy, sensitivity, reproducibility).
    - Evaluation of patterns in ctDNA concentrations and their use for monitoring (tumor progression, relapse detection, treatment-effect assessment).
    - Assessment of whether ctDNA-guided therapy changes are associated with improved outcomes.
- Project structure and readiness
    - Grant Category: Pilot Grant; Research Category: Innovation
    - Florida-based research with access to needed technologies/resources and partnerships.

Project Title: Building on Trust: Navigating Preventive Lung, Breast, and Prostate Cancer Screenings at Community Resource Spots
Principal Investigator: Leerin Shields
Institution: Adventist Health System/Sunbelt, Inc.
Funding: $1,703,501.00
Cancer type: Lung, Breast, Prostate

Goals or projected outcomes

- Increase adherence to USPSTF screening guidelines for lung, breast, and prostate cancers among adults facing social and structural barriers.
- Reduce disparities in cancer care by improving screening uptake, timely diagnosis, and access to treatment.
- Evaluate the impact of combining routine cancer screening with a navigation team in community-based settings (rural, suburban, urban).
- Build a sustainable, community-anchored screening model by partnering with established organizations and understanding reasons behind care decisions.

Population to be served

- Medically underserved adults, specifically unhoused and resource-insecure individuals.
- Adults reached through rural, suburban, and urban community-based health settings in Central Florida.

Research methods or project implementation plan

- Design and framework: Prospective, mixed-methods implementation science study.
- Intervention setting: Pop-up screening clinics sited at “community resource spots” in partnership with well-established community-based organizations.
- Core components:
    - Routine screening for lung, breast, and prostate cancers aligned to USPSTF guidelines.
    - A team of navigators to connect those with positive results to community health resources, financial advocacy, care coordination, and access to clinical trial screening.
- Evaluation activities: Surveys and interviews to identify barriers, assess acceptability/feasibility, and inform sustainability; track screening uptake and timely follow-up of abnormal findings.
- Intended outcomes: Improved screening adherence, faster linkage to diagnosis/treatment, and a scalable model for underserved communities.

Project Title: A Prospective Study of a Lifestyle Medicine Survivorship Program for Patients with Gynecologic Cancer
Principal Investigator: Amanda Sawyer
Institution: Adventist Health System/Sunbelt, Inc.
Funding: $535,861.00
Cancer Type: Gynecologic

Goals or projected outcomes

- The way women with gynecological cancers live their daily lives – through exercise, nutrition, sleep, stress management, and other lifestyle habits – can have a significant impact on their recovery and overall well-being. Studies have shown that adopting healthy habits like eating nutritious food, staying active, sleeping well, and reducing stress can improve both physical and mental health for patients with cancer. On the other hand, patients who do not engage in these healthy behaviors often experience more side effects from their cancer treatment and disease. While this has been shown in cancers like breast and colorectal cancer, there is an opportunity to explore the impact of these lifestyle factors in women with gynecologic cancers. A program called the Healthy Eating Active Lifestyle (HEAL)-GYN was developed to address this gap.

Population to be served

- Women with gynecological cancer.

Research methods or project implementation plan

- This program provides intensive lifestyle coaching over eight weeks, where women with gynecological cancer participate in virtual group sessions.
- These sessions are led by a team of healthcare professionals, including an oncologist, registered dietician, and exercise expert, and offer information, education, and social support.
- The weekly 90-minute sessions cover a range of topics, including healthy eating, strength training, improving sleep, managing stress, and building social connections. Patients also have live demonstrations to teach them practical skills like meal preparation and yoga.
- Throughout the program, participants set personal, achievable goals to help them make lasting changes. After the program, ongoing support continues through coaching and private social media groups, ensuring that patients stay on track with their new behaviors.
- This continuous support is essential for maintaining lifestyle changes after the program ends.

Project Title: Reducing Cancer Health Disparities in Florida through Functional Precision Medicine and Artificial Intelligence - Pilot Study serving Minority, Underserved Cancer Patients.
Principal Investigator: Noah Berlow
Institution: First Ascent Biomedical
Funding: $2,000,000.00
Cancer type: Other (Special) – Precision Medicine

Goals or projected outcomes

- Provide local, personalized cancer treatments to minority, underserved rural communities in Florida using a “biopsy-to-lab-to-local care” model powered by functional precision medicine and AI.
- Eliminate financial and travel barriers by centrally testing biopsies in Miami, returning results to local doctors, and subsidizing off-label drug costs when appropriate.
- Bridge gaps by extending precision medicine—traditionally limited to major centers—to community settings across Florida.
- Pilot and demonstrate feasibility of this model to improve access and outcomes for underserved populations.

Population to be served

- Minority patients—specifically Black and Brown communities—in rural and underserved areas across Florida.
- Multiple special populations are indicated; data collection from the targeted groups begins immediately.

Research methods or project implementation plan

- Care pathway and technology
    - Collect patient biopsies locally; perform centralized functional precision testing in a Miami laboratory.
    - Use AI to support treatment selection; transmit results back to local clinicians to deliver care close to home.
    - Subsidize off-label medication costs, when appropriate, to overcome insurance denials noted in the application.
- Project structure and readiness
    - Grant Category: Pilot Grant; Research Category: Innovation.
    - Access to required innovative technologies/resources: Yes; partnerships/agreements established in less than 3 months.
    - Special populations: Multiple; measures/outcomes tailored; data collection starts immediately.

Project Title: The Live Like Bella® Comprehensive Childhood Cancer Network
Principal Investigator: Nicole de Lara Puente
Institution: Live Like Bella Childhood Cancer Foundation
Funding: $2,000,000.00
Cancer type: Brain (Glioblastoma)

Goals or projected outcomes

- Build a comprehensive, wrap-around care model that unites clinical, social, and community resources to improve outcomes for pediatric cancer patients in Florida.
- Reduce family distress, improve adherence to treatment plans, and enhance overall well-being through structured psychosocial support and navigation.
- Increase participation in Florida-based pediatric oncology clinical trials by facilitating access, providing financial support, and streamlining recruitment via a secure portal.
- Address disparities in healthcare access and improve continuity of care by sharing best practices among public and private partners.

Population to be served

- Primary: Children with cancer in Florida and their families/caregivers, including siblings.
- Secondary: Pediatric oncology providers and research teams in Florida who will use best practice resources and the trial recruitment portal.

Research methods or project implementation plan

- Objective 1: Comprehensive Access Program
    - Develop a real-time, comprehensive family support and navigation guide for families with a child battling cancer.
    - Provide structured psychosocial support, educational resources, and access to critical services for the diagnosed child and siblings.
    - Expected results: Reduce distress, improve treatment adherence and well-being, and facilitate access to Florida clinical trials with financial support to increase participation.
- Objective 2: Clinical Trial Recruitment & Resource Guide
    - Build a secure, customized portal to streamline trial recruitment with real-time information on available trials, eligibility, and logistics for families and providers.
- Project structure and readiness
    - Grant category: Pilot Grant (innovative approach to energize collaborations and break down silos).
    - Research focus/type: Best Practices and Patient & Family Support (patient engagement begins immediately; access to patient support networks is already in place; methods to measure engagement are identified).
    - Category alignment: Best Practices; agreements/partnerships exist, with any additional partnerships anticipated within 3–6 months.
    - Deployment: Patient engagement/support mechanisms commence immediately; tools and guides are designed for ongoing, real-time use by families and providers.

Project Title: PANDA: Advanced AI-Driven Diagnostic Tool for Early Detection and Improved Outcomes in Pancreatic Cancer
Principal Investigator: Bryan Allinson
Institution: Vanquish Bio, Inc.
Funding: $1,996,312.00
Cancer type: Pancreatic

Goals or projected outcomes

- Enable early, real-time detection and differentiation of pancreatic lesions (cystic neoplasms and solid tumors) during standard EUS procedures.
- Reduce reliance on operator skill and variability by providing AI decision support at the point of care.
- Achieve regulatory readiness: finalize FDA submission documentation (PMA or De Novo), informed by expanded validation data.
- Deploy a cloud-based solution with appropriate privacy/security safeguards (HIPAA guidelines referenced).
- Validate performance on a larger Orlando Health dataset, building on preliminary results (97% sensitivity, 99% specificity in blinded runs).

Population to be served

- Patients in Florida undergoing pancreatic EUS (including those with suspected pancreatic lesions).
- Florida care ecosystem participants via collaboration among Vanquish Bio (Vanquish Oncology), Orlando Health, and the University of Central Florida.

Research methods or project implementation plan

- Approach and setting
    - Integrate AI into the live EUS workflow to detect and characterize pancreatic lesions in real time.
    - Focus on improving sensitivity/specificity while minimizing operator dependency and unnecessary invasive confirmations.
- Data and validation
    - Build on preliminary Orlando Health experience (>150 pancreas EUS procedures; >45,000 frames from 269 patients; blinded runs).
    - Validate PANDA on a larger Orlando Health dataset to optimize the model prior to clinical study.
- Regulatory and compliance
    - Proceed toward FDA PMA or De Novo pathways per prior FDA feedback.
    - Finalize FDA submission documents with new validation data; establish HIPAA-related guidelines for cloud deployment/data handling.
- Project structure
    - Consortium Grant with Florida partners: Vanquish Bio (lead), Orlando Health, and the University of Central Florida.
    - Required partnerships/resources expected within less than 3 months.
    - Technology transfer timeline indicated for commercial readiness within 1 year after the grant period.

Project Title: Developing a biodegradable stent to protect patients from post-surgical anastomotic leaks (AL) following rectal cancer surgery
Principal Investigator: Scott Kelley
Institution: SafeGuard Surgical, Inc.
Funding: $1,994,665.00
Cancer type: Colon

Goals or projected outcomes

- Avoid the need for temporary stomas (and reversal operations) by protecting the anastomosis during healing.
- Mitigate the sequelae of anastomotic leaks (ALs) and reduce associated costs, morbidity, and mortality.
- Improve patients' quality of life by eliminating external ostomy bags when possible.
- Advance a device (LeakGuard) with FDA Breakthrough Device designation that could "revolutionize management of rectal and other cancers."

Population to be served

- Patients undergoing colorectal cancer surgery requiring resection and anastomosis (noting the document's emphasis that ~40% of colorectal cases involve the rectum).
- Florida-based research beneficiaries within the state's cancer care ecosystem.

Research methods or project implementation plan

- Device concept and use
    - LeakGuard is a temporary, biodegradable intraluminal barrier placed during surgery to divert/contain contents and protect the anastomosis during the critical healing phase.
    - It is designed to hydrolyze, degrade, and pass naturally, obviating the need for a removal procedure.
- Development status and ownership
    - Safeguard Surgical owns the intellectual property, has developed a prototype, and reports initial proof-of-concept efforts (text truncated in the provided excerpt).
    - The device has received FDA Breakthrough Device designation (CDRH).
- Intended/expected outcomes from implementation
    - Avoid ostomy creation and subsequent reversal operations.
    - Decrease costs, morbidity, and mortality tied to ALs.
    - Improve patient quality of life.

Project Title: Advancing Precision Medicine for Pediatric Oncology with Whole Genome Sequencing (WGS) and Clinical Trials Matching
Principal Investigator: David Seo
Institution: Nicklaus Children's Health System
Funding: $1,957,615.00
Cancer type: Other (Special) – Pediatric Oncology

Goals or projected outcomes

- Identify novel and actionable biomarkers in pediatric cancers by performing whole genome sequencing (WGS) and quantifying added value beyond prior panel-based testing.
- Automate genomic analysis and reporting to simplify clinician interpretation by deploying the Sylvester Data Portal (SDP) at Nicklaus Children's Health System (NCHS), integrating EHR data and generating clinician-friendly reports.
- Improve access to treatment options by providing AI-powered, personalized clinical trial and pediatric oncology provider matching in Florida.
- Advance an achievable precision medicine approach for underserved pediatric oncology patients in Florida.

Population to be served

- Pediatric oncology patients (special population) in Florida.
- Underserved pediatric oncology patients specifically referenced as beneficiaries

Research methods or project implementation plan

- Aim 1: Whole Genome Sequencing and biomarker discovery
    - Sequence 100 pediatric cancer samples from the NCHS tissue bank.
    - Compare WGS results to prior panel-based tests to assess added clinical value.
    - Annotate variants using databases (e.g., ClinVar, COSMIC) to identify actionable findings.
- Aim 2: Clinical deployment of automated WGS reporting
    - Deploy the Sylvester Data Portal (SDP) at NCHS for clinical WGS integration.
    - Automate sequencing data ingestion and EHR integration.
    - Generate clinician-friendly reports to support genomic decision-making.
- Aim 3: AI-powered clinical trial and provider matching
    - Develop AI tools to match pediatric patients to relevant clinical trials and pediatric oncology providers in Florida.
    - Provide personalized recommendations to improve awareness and access to treatment opportunities statewide.
- Project structure
    - Grant Category: Consortium Grant (2 partners; cross-disciplinary; 2 new partners); Research Category: Innovation.
    - Special Populations: Pediatric Populations (data collection to begin within 3 months; measures/outcomes tailored to this population; partnerships and innovative resource access within <3 months; innovative technologies available).

Project Title: Targeting Lipid Signaling in Refractory and Aggressive Cancers
Principal Investigator: Jun Zhao
Institution: Cleveland Clinic Florida
Funding: $571,582.00
Cancer types: Non-Hodgkins Lymphoma, Breast, Brain

Goals or projected outcomes

- Advance lead compounds that inhibit PIKFYVE and PIP4K2C—kinases not currently targeted by approved drugs—into optimized therapeutic candidates.
- Use medicinal chemistry and rational design to improve potency, selectivity, and anti-cancer activity (building on >100 synthesized analogs).
- Demonstrate strong pharmacological/biochemical profiles and anti-cancer effects to support translational readiness for difficult-to-treat cancers.

Population to be served

- Patients in Florida with refractory and aggressive cancers, specifically:
    - Non-Hodgkin lymphoma (including virus-positive, refractory, and relapsed subtypes)
    - Triple-negative breast cancer
    - Pediatric patients with diffuse intrinsic pontine glioma (DIPG)
- Contact points (hotlines and website/email)

Research methods or project implementation plan

- Core approach
    - Build on small-molecule screening that identified potent, selective inhibitors of PIKFYVE and PIP4K2C.
    - Apply medicinal chemistry and rational design to generate and refine analogs (already >100) that further boost activity and selectivity.
    - Conduct cutting-edge pharmacological and biochemical analyses to characterize target engagement, selectivity, and anti-cancer activity.
- Project structure and readiness
    - Grant category: Standard Grant; Research category: Innovation
    - Research type: Translational Research; phase anticipated to begin within 6 months
    - Access to required innovative technologies/resources: Yes; additional partnerships expected in <3 months

Project Title: Cardio-Oncology Consortium to evaluate and improve the cardiovascular care of cancer patients in Florida utilizing the Global Cardio-Oncology Registry (G-COR) platform.
Principal Investigator: Diego Sadler
Institution: Cleveland Clinic Florida
Funding: $625,822.00
Cancer type: Breast

Goals or projected outcomes

- Scale the G COR platform statewide to standardize early detection, surveillance, and cardioprotection for cancer treatment–related cardiovascular toxicities (CTR CVT).
- Generate real-world evidence on CTR CVT incidence and outcomes across Florida cancer centers.
- Develop and disseminate Florida-specific best practice protocols to improve survival and care quality.
- Leverage the validated G COR pilot (700 breast cancer patients, 19 U.S. hospitals) to accelerate implementation.

Population to be served

- Cancer patients at academic and community sites in the Florida G COR consortium.
- Priority groups: breast cancer, hematologic malignancies, and patients on immune checkpoint inhibitors.
- Patients at risk for CTR CVT, with data on cardiovascular risk, disease, treatment, and outcomes.

Research methods or project implementation plan

- Design and platform
    - Prospective, multicenter cohort registry using the G-COR infrastructure.
    - De-identified data entered into REDCap Cloud; hosted by Cleveland Clinic Cancer Center.
- Site activation and governance
    - Each site secures IRB approval and completes protocol/database training prior to activation.
    - Consortium model includes 4+ cross-disciplinary partners, including new and underserved-area sites.
- Data elements and follow-up
    - Detailed capture of cancer type, treatment, functional status, CV risk, imaging, and socioeconomic data.
    - Prospective follow-ups at 3, 6, and 12 months.
- Best-practices focus and deliverables
    - Use registry data to streamline and standardize Florida practices for early detection, surveillance, and cardio protection.
    - Produce Florida protocols to be shared among public and private entities.
- Project structure and readiness
    - Grant Category: Consortium Grant; Research Category: Best Practices.
    - Research Type: Treatment-Related Morbidities.
    - Access to multidisciplinary resources and preliminary tools: Yes.

- Anticipated ability to gather morbidity data in non-cancer systems: 6–12 months after study initiation.

Project Title: Artificial Intelligence-Driven Support for Distress Management in Patients with Cancer
Principal Investigator: Zeina Nahleh
Institution: Cleveland Clinic Florida
Funding: $142,784.00
Cancer type: Other (Special) – All types of cancer on stage I, II and III, currently undergoing treatment at Maroone Cancer Center, Cleveland Clinic Florida.

Goals or projected outcomes

- Evaluate the impact and feasibility of an AI-driven chatbot (Wysa) used at home, alongside standard psychological care, to improve mental health and quality of life in patients with cancer.
- Improve outcomes specifically in anxiety, depression, and overall quality of life.
- Provide continuous, remote psychological support beyond clinic appointments using validated techniques (CBT and mindfulness).

Population to be served

- Adults with stage I–III cancers of any type who are currently undergoing treatment at the Maroone Cancer Center (Cleveland Clinic Florida).
- Florida-based oncology patients, addressing an identified gap in accessible behavioral health support.

Research methods or project implementation plan

- Design: Two-arm study with 70 total participants (35 per arm).
  - Intervention: Standard psychological care plus at-home use of the Wysa AI chatbot delivering CBT/mindfulness-based support.
  - Comparator: Standard psychological care (implied by the “complementary” framing).
- Key measures: Mental health and quality of life, including outcomes such as anxiety and depression; feasibility and engagement with the AI tool.
- Setting and delivery: Remote, daily chatbot support to extend care beyond scheduled visits; conducted at the Maroone Cancer Center.
- Project structure and readiness
  - Grant category: Pilot Grant; Research category: Innovation; Research type: Patient and Family Support.
  - Access to required innovative technologies: Yes.
  - Patient support networks available; methods identified to measure patient/family engagement.
  - Partnerships/resources timeline: 3–6 months.
  - Patient engagement/support mechanisms: Implemented immediately.

Project Title: A Twin SQL and Smart Cancer Repository and Query System with Analytical Intelligence Capability and Shared Access
Principal Investigator: Nezamoddin Kachouie
Institution: Florida Institute of Technology
Funding: $600,071.00
Cancer type: Lung

Goals or projected outcomes

- Centralize and unify cancer data: Create a single repository for clinical, genomic, imaging, treatment, and outcomes data to enable efficient access and analysis.
- Enhance decision-making: Provide personalized treatment planning and real-time clinical support using advanced analytics and predictive modeling.
- Accelerate research: Enable intelligent data mining to discover patterns, biomarkers, and treatment efficacy; support clinical trial discovery.
- Inform public health: Generate population-level insights to guide prevention policies and optimize resource allocation.
- Usability and transparency: Deliver dashboards/visualizations and a continuous learning feedback loop to improve analytics over time.

Population to be served

- Direct users: Florida clinicians, researchers, and public health teams needing secure, rapid access to integrated oncology data and analytics.
- Indirect beneficiaries: Florida cancer patients and broader populations, via improved evidence-based care, research acceleration, and policy planning.

Research methods or project implementation plan

- Data architecture and integration
    - SQL Server–based, scalable repository supporting structured and unstructured oncology data.
    - Integrations with multiple sources (e.g., EHRs, imaging centers, clinical trial databases).
- Smart query and analytics layer
    - Natural-language interface powered by Large Language Models (LLMs) that translate user questions into SQL/API calls.
    - Semantic search and contextual recommendations to improve discovery.
    - Descriptive, predictive, and prescriptive analytics with dashboards/visualizations for intuitive results.
- Learning system and governance
    - Continuous feedback loop to refine models/queries as data and user input evolve.
    - Privacy and compliance measures including encryption and de-identification.
- Project structure
    - Grant category: Pilot Grant; Research category: Data and Statistics
    - Data/DUA readiness: Data or agreements expected in less than 3 months.
    - Open sharing cadence: Quarterly updates on shared findings/progress.

Project Title: A Multimodal Lung Cancer Risk Assessment Model using Comprehensive Data Integration
Principal Investigator: Nezamoddin Kachouie
Institution: Florida Institute of Technology
Funding: $422,453.00
Cancer type: Lung

Goals or projected outcomes

- Deliver precise, individualized risk assessments using comprehensive multimodal data.
- Support clinical decision-making (e.g., tailoring screening protocols and therapeutic strategies).
- Enable dynamic, continuously updated risk predictions as new information becomes available.
- Identify high-risk populations to inform public health resource allocation.
- Reduce the burden of high-stage cancers and improve survival by advancing data-driven, real-world oncology applications.
- Bridge research and practice via highly accurate and actionable risk scores.

Population to be served

- Patients with or at risk for lung cancer in Florida (project title: “A Multimodal Lung Cancer Risk Assessment Model”).
- Clinical teams and public health stakeholders who will use risk scores to guide screening, treatment planning, and population-level interventions.

Research methods or project implementation plan

- Core approach and architecture
    - Integrate heterogeneous data (demographics, clinical factors/records, gene mutations, environmental and behavioral factors, lifestyle; plus radiomics and patient histories) within a unified predictive framework.
    - Build robust data pipelines for ingestion, cleaning, transformation, and structuring of raw data.
    - Apply modern machine learning for clinical text analysis and explainable statistical methods (e.g., Bayesian inference) to produce interpretable risk scores.
    - Use multimodal learning to fuse radiomics with clinical histories; apply temporal analysis to track and update risk over time.
    - Employ advanced feature selection to emphasize critical predictors and improve accuracy and clinical relevance.
- Expected outputs and use
    - Clinician-facing, interpretable risk scores to tailor screening and interventions.
    - Population-level insights that highlight high-risk groups for targeted public health action.
- Project structure and readiness
    - Grant Category: Standard Grant; Research Category: Data and Statistics.
    - Research Type: Implementation Research; time to implement clinical practices once the study begins: 3–6 months.
    - Data/DUA readiness: Data or data use agreements anticipated within less than 3 months.

Project Title: MBLAC1: A Novel Target for the Treatment of Glioblastoma
Principal Investigator: Anna Knapinska
Institution: Florida Atlantic University
Funding: $561,276.00
Cancer type: Brain

Goals or projected outcomes

- Selectively inhibit glioblastoma growth by targeting MBLAC1 and disrupting copper (Cu1+)-dependent mitochondrial functions in tumor cells while sparing healthy neurons and glia.
- Define the mechanistic role of MBLAC1 in glioblastoma, extending prior work beyond C. elegans to knockout mice and human GBM studies.
- Use and refine advanced 3D glioblastoma invasion models to evaluate anti-invasive and anti-tumor efficacy and support preclinical drug screening.
- Timeline noted in the application: treatment efficacy findings anticipated more than 12 months after study start.

Population to be served

- Ultimate beneficiaries: Patients with glioblastoma (Florida-based research effort).
- Immediate study models: Multiple human glioma cell lines in 3D spheroid/hydrogel systems; planned mechanistic analyses in MBLAC1 knockout mice and human GBM contexts.

Research methods or project implementation plan

- Model platform and rationale
    - Employ 3D tumor spheroids embedded in hydrogels (e.g., collagen) to closely mimic in vivo invasion through ECM/basement membrane—an approach pioneered by the PI's lab and previously used to evaluate anti-invasive treatments.
    - Utilize this platform for predictive, preclinical screening of MBLAC1-targeted interventions.
- Mechanistic focus
    - Investigate MBLAC1 as a regulator of Cu1+ homeostasis linked to tumor mitochondrial function and invasion.
    - Extend mechanistic analyses to knockout mice and human GBM models to clarify MBLAC1's role and therapeutic potential.
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation
    - Research type: Treatment Studies
    - Access to required innovative technologies/resources: Yes; formal partnerships in place; time to establish any additional resources/partnerships: less than 3 months
    - Anticipated reporting of treatment efficacy: more than 12 months

Project Title: Targeting actin-microtubule network to enhance taxane efficacy in advanced prostate cancer
Principal Investigator: Michael Lu
Institution: Florida Atlantic University
Funding: $274,558.00
Cancer type: Prostate

Goals or projected outcomes

- Enhance taxane efficacy in advanced prostate cancer by destabilizing the actin–microtubule network through inhibition of the PAK6–LIMK1 signaling axis.
- Overcome tumor resistance to taxanes and broaden the fraction of patients who benefit from taxane chemotherapy.
- Define “cytoskeleton signatures” associated with heightened taxane sensitivity (e.g., loss of transverse actin stress fibers and focal adhesions; elongated CLASP2/CLIP170 comets on microtubules).
- Advance small-molecule inhibitors (targeting PAK6–LIMK1) as taxane sensitizers within an innovative, cytoskeleton-focused paradigm.

Population to be served

- Men with advanced prostate cancer receiving taxanes:
    - Metastatic castration-resistant prostate cancer (mCRPC) after androgen deprivation therapy (ADT).
    - Metastatic castration-sensitive prostate cancer (mCSPC), where taxanes are increasingly combined with ADT.
- Immediate work centers on prostate cancer cell models; the clinical intent is to benefit Florida patients with advanced prostate cancer.

Research methods or project implementation plan

- Rationale/innovation
    - Move beyond non-specific omics/meta-analysis approaches to taxane sensitization by directly targeting newly identified cytoskeletal regulators (PAK6–LIMK1) to destabilize the actin–microtubule network.
- Experimental approach (preclinical)
    - Gene perturbation: CRISPR-Cas9 PAK6 knockout markedly sensitizes prostate cancer cells to taxanes and induces characteristic cytoskeletal changes (loss of actin stress fibers/focal adhesions; elongated CLASP2/CLIP170 comets).
    - Pharmacology: Apply small-molecule inhibitors of the PAK6–LIMK1 axis to reproduce cytoskeletal destabilization and test for potentiation of taxane cytotoxicity.
    - Readouts (as described): Cytotoxic response to taxanes and cytoskeletal phenotype “signatures” indicative of enhanced sensitivity.
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation; Open Science: Yes (progress shared annually).
    - Access to needed innovative methods/resources: Yes; timeline to establish any additional partnerships/resources: >6 months.

Project Title: Exploring the feasibility of an exercise and noninvasive brain stimulation intervention in breast cancer survivors
Principal Investigator: Ashley Artese
Institution: Florida Atlantic University
Funding: $159,626.00
Cancer type: Breast

Goals or projected outcomes

- Establish feasibility of a multi-domain intervention that combines aerobic exercise with transcranial alternating current stimulation (Ex+tACS) in breast cancer survivors reporting CRCI.
- Compare pre- to post-intervention changes in cognition between Ex+tACS and a control group receiving exercise plus sham tACS, using both objective and subjective measures.
- Generate foundational data on potential cognitive benefits to inform implementation strategies for future research trials and clinical care.

Population to be served

- Breast cancer survivors who report CRCI.
- Target sample: 40 participants (Florida-based; led by Florida Atlantic University).

Research methods or project implementation plan

- Design: Randomized allocation of 40 breast cancer survivors to
    - Ex+tACS: Exercise plus active tACS
    - Control (CON): Exercise plus sham tACS
- Intervention: 4 weeks, three sessions per week
    - 30 minutes of moderate-intensity treadmill exercise
    - Followed by 15 minutes of tACS
    - During tACS: AX-Continuous Performance Test (AX-CPT) to assess contextual processing, cognitive control, and sustained attention
- Cognitive assessments
    - Executive function: Trail Making Test Part A (TMT-A) and Part B (TMT-B)
    - Inhibitory control: assessment noted but the test name is truncated in the provided excerpt
    - Subjective cognition: pre- to post-intervention comparisons (as stated)
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation
    - Research type: Treatment Studies
    - Innovation: First to combine exercise and non-invasive brain stimulation in breast cancer survivors (using portable NIBS) with comprehensive cognitive assessments
    - Partnerships/resources: Access confirmed; additional partnerships expected in <3 months
    - Anticipated timing for reporting treatment efficacy: More than 12 months

Project Title: Heart of Florida Health Center, Cancer Screening and Access to Care Project (CSACP)
Principal Investigator: Nicholas Dorsey
Institution: Heart of Florida Health Center, Inc.
Funding: $968,544.00
Cancer type: Breast, Colon, Skin, Gynecologic

Goals or projected outcomes

- Increase the number and percentage of individuals screened for colorectal, cervical, breast, and skin cancers.
- Ensure patients with abnormal screening results receive follow-up care within 30 days.
- Educate the community on the importance of cancer prevention and early detection.
- Reduce disparities in prevention and early detection among vulnerable groups in Marion County, Florida.

Population to be served

- Underserved HFHC patients in Marion County, Florida, including:
    - Low-income, uninsured, and rural residents.
- Individuals eligible for colorectal, cervical, breast, and skin cancer screenings identified via existing health information technology.

Research methods or project implementation plan

- Design and approach
    - Mixed-methods project integrating clinical interventions with community outreach.
    - Deploy advanced screening tools:
        - AI-assisted DermaSensor for skin cancer screening.
        - Self-collected and traditional HPV/PAP testing for cervical cancer.
        - FIT testing for colorectal cancer.
    - Use existing health information technology to identify screening-eligible patients.
    - Provide personalized patient navigation and case management to ensure timely follow-up and address barriers (transportation, language, financial).
- Process and timelines
    - Track abnormal results and facilitate follow-up care within 30 days.
    - Conduct community education on prevention and early detection.
- Data and evaluation
    - Establish baseline screening rates and set health center goals aligned with established quality-of-care measures.
    - Monitor screening uptake across targeted cancers and completion of follow-up after abnormal results.

Project Title: Mitigation of Chemotherapy-induced Nephrotoxicity via Podocyte Protection
Principal Investigator: Darlah Lopez
Institution: 149 BIO, LLC
Funding: $941,944.00
Cancer type: Other (Special) – Kidney damage associated with cancer treatment

Goals or projected outcomes

- Protect kidneys during cancer therapy by preserving podocyte adhesion and preventing injury cascades that lead to AKI, CKD, and proteinuria.
- Develop and optimize specific agonist antibodies to integrin VLA3 (critical for podocyte anchoring to the glomerular basement membrane) to stabilize podocyte function under chemotoxic stress.
- Deliver candidates with high affinity, strong developability, and high specificity (targeted >50× selectivity over VLA6 and LFA-1).
- Show preclinical efficacy in murine models of chemotherapy-induced nephrotoxicity (e.g., Adriamycin), with outcomes including reduced proteinuria and preserved podocyte/glomerular architecture.

Population to be served

- Cancer patients in Florida receiving chemotherapy, targeted therapy, or immunotherapy who are at risk for therapy-induced kidney injury (AKI/CKD/proteinuria) due to podocyte loss/dysfunction.

Research methods or project implementation plan

- Antibody discovery and optimization
    - High-content screening (HCS) platform with machine learning–guided antibody optimization using VLA3-based assays to generate and refine scFv antibodies.
    - Iterative AI-driven design to improve binding affinity, specificity (>50× selectivity vs VLA6 and LFA-1), and developability.
- Antibody engineering
    - Reformat top scFv candidates into full-length, monovalent IgG constructs.
    - Fc engineering to reduce ADCC and extend half-life via enhanced FcRn recycling.
- Biophysical and functional validation
    - Epitope mapping by alanine scanning.
    - Binding kinetics by Bio-Layer Interferometry (BLI).
- In vivo efficacy (preclinical)
    - Test candidates in murine models of chemotherapy-induced nephrotoxicity (e.g., Adriamycin-induced injury).
    - Primary outcomes: reductions in proteinuria; preservation of podocyte and glomerular architecture.
- Project structure
    - Research category: Innovation.
    - Research type: Translational Research; targeted Phase I start: more than 12 months.
    - Access/partnerships timeline for innovative resources: more than 6 months.

Project Title: Rapid, low-cost early detection test for lung cancer
Principal Investigator: Elizabeth Franzmann
Institution: Vigilant Laboratories
Funding: $882,198.00
Cancer type: Lung

Goals or projected outcomes

- Develop a simple, rapid, inexpensive oral-rinse–based point-of-care (POC) screening test for lung cancer.
- Test whether a small biomarker panel (CD44, p16, total protein) measured with a portable reader can sensitively and specifically distinguish lung cancer cases from controls.
- Discover and add additional proteomic markers (via single-cell/proteomic approaches) to improve accuracy of an oral “liquid biopsy.”
- Address access gaps of LDCT screening (noted limited access/adoption and risks), especially by offering a noninvasive, accessible alternative suitable for broader use.

Population to be served

- Individuals at risk for or with lung cancer in Florida.
- Initial study cohort:
    - 50 lung cancer patients (from cardiothoracic surgery clinics)
    - 50 controls (25 smokers, 25 non-smokers)

Research methods or project implementation plan

- Aim 1: Point-of-care biomarker testing
    - Collect oral rinses from 50 lung cancer cases and 50 controls (25 smokers, 25 non-smokers).
    - Quantify CD44, p16, and total protein (TP) using POC assays and a handheld reader.
    - Compare biomarker levels between cases and controls; evaluate effects of age, race, gender, and tobacco use.
    - Outcome: Determine feasibility and performance of a small oral biomarker panel and device for early detection.
- Aim 2: Single-cell/proteomic characterization
    - Perform high-dimension, 40-color spectral flow cytometry on oral-rinse cells from the same 50 cases and 50 controls.
    - Characterize protein marker expression across hematopoietic and other oral cell populations (as specified in the full protocol).
    - Use proteomic discovery to identify additional markers that could augment the POC panel.
- Project structure and readiness
    - Grant category: Consortium Grant; Research category: Innovation.
    - Access to required innovative technologies/resources: Yes; partnerships/resources expected within <3 months.
    - Technology Transfer Feasibility: Preliminary IP plan and commercial interest identified; readiness for commercial interest within 1 year.

Project Title: Digital Biomarkers of Stress Response During and After Breast Cancer Treatment
Principal Investigator: Christian Poellabauer
Institution: Florida International University
Funding: $842,236.00
Cancer type: Breast

Goals or projected outcomes

- Develop digital biomarkers (from mobile/wearable physiological signals) to detect, quantify, and predict mental health problems common in cancer (e.g., anxiety, depression, sleep issues, fatigue).
- Use these biomarkers to clarify how cancer treatment relates to psychological stress during and after therapy.
- Produce AI-enabled, continuous measures that can augment or replace traditional biomarkers (e.g., saliva-based) to support timely identification and management of stress-related morbidities.
- Enable improvements in quality of life and overall health by addressing a frequently neglected dimension of cancer care.

Population to be served

- Breast cancer patients and survivors in Florida, during and after treatment.

Research methods or project implementation plan

- Data collection: Use state-of-the-art mobile/wearable sensors to capture physiological indicators of stress and related symptoms (e.g., sleep disturbance, persistent physical complaints).
- AI/digital biomarker development: Build and validate models that detect, quantify, and predict the onset and course of mental health problems from physiological signals.
- Comparative utility: Design biomarkers to augment or potentially replace traditional approaches (noted example: saliva-based measures).
- Focus and scope: Examine stress as a treatment-related morbidity, emphasizing both active treatment and survivorship phases; center the analysis on breast cancer.

Project Title: CancerAIKG: a Web-scale Trustworthy AI-Knowledge Graph-LLM hybrid on Cancer, Constructed and Interrogated for Bias using Deep-Learning
Principal Investigator: Michael Gubanov
Institution: Florida State University
Funding: $1,199,987.00
Cancer type: Breast, Colon, Bladder

Goals or projected outcomes

- Provide clinicians with precise, targeted answers supported by extracted facts by combining a Large Language Model (LLM) with a Knowledge Graph (KG) as a "guide-rail."
- Revolutionize access to best practices dispersed across millions of publications by enabling efficient retrieval, organization, and synthesis for individual patients.
- Mitigate key LLM limitations—hallucinations, catastrophic forgetting, outdated training data, and high retraining costs—through KG-guided retrieval and scalable updating.
- Deliver a scalable, trustworthy decision-support capability that improves cancer care in Florida.

Population to be served

- Direct users: Florida oncologists/clinicians who need timely access to best practices and personalized evidence.
- Indirect beneficiaries: Florida cancer patients who receive care informed by more accurate and current guidance.
- Consortium context: 3 partners, cross-disciplinary, ≥200 miles apart, includes partners in underrepresented/access-desert areas.

Research methods or project implementation plan

- System architecture
    - Search engine: Retrieves relevant items from millions of recent publications.
    - Knowledge Graph: Structures extracted facts and constrains LLM outputs to reduce hallucinations and maintain precision.
    - LLM interface: Provides an intuitive, clinician-facing experience; uses the KG as a guard-rail for accurate, targeted responses.
- LLM limitation mitigation
    - Address hallucinations, catastrophic forgetting, outdated training data (e.g., legacy cutoffs), and high retraining costs via KG-guided retrieval and focused updates rather than full model retrains.
- Best Practices alignment and readiness
    - Research Category: Best Practices.
    - Access/agreements to share best practices: Indicated as in place at submission (time to establish: N/A).
- Technology transfer feasibility
    - Stated readiness for commercial interest or company formation: within 1 year after the grant period.

Project Title: Pre-Clinical Studies of Splicecosomal Immunomodulators in Combination with Checkpoint Inhibitors in Humanized Melanoma Mouse Model
Principal Investigator: Dmitriy Minond
Institution: Nova Southern University
Funding: $424,289.00
Cancer type: Skin

Goals or projected outcomes

- Validate synergy between spliceosomal inhibitor 2155-18 and FDA-approved immune checkpoint inhibitors (anti–CTLA-4, anti–PD-1).
- Establish hnRNPH1/H2 targeting as a novel therapeutic strategy to boost ICI efficacy, especially in low-response melanoma subtypes.
- Generate preclinical data (tumor inhibition, survival) to support further development of spliceosomal immunomodulators as ICI combination partners.

Population to be served

- Immediate: Humanized NSG SGM3 mice engrafted with low-TMB, MSS human melanoma PDX (J000106560/PS4050).
- Ultimate: Melanoma patients with poor ICI response, particularly in Florida-based clinical contexts.

Research methods or project implementation plan

- Model: NSG SGM3 mice with functional human immune compartments; PDX sourced from Jackson Laboratory.
- Dosing and schedule
  - 2155-18: subcutaneous, 3×/week for 21 days
  - ICIs: intraperitoneal, every 4th day
- Assessments
  - Tumor volume (biweekly caliper measurements)
  - Survival analysis with Kaplan–Meier curves.
- Statistical plan and sample size
  - With 10 mice/group: 80% power to detect 1.33 SD difference; 89% power for 1.5 SD difference.
  - Plan for ≥10 mice/group; increase to 12/group if effects are more subtle (12 × 7 groups = 84 mice).
- Project structure
  - Grant Category: Standard Grant; Research Category: Innovation
  - Research Type: Treatment Studies
  - Anticipated timeline to report treatment efficacy findings: 6–12 months

Project Title: Development of Genetically Engineered Smart Exosomes for Targeted Treatment of Cancer
Principal Investigator: Mandip Sachdeva
Institution: Florida A&M
Funding: $281,879.00
Cancer type: Breast, Pediatric

Goals or projected outcomes

- Advance PDLE-S3, a targeted exosome-based immunotherapy, to overcome cancer immunosuppression and drive tumor regression.
- Test synergy with chemotherapy and assess safety in humanized mouse models.
- Generate preclinical data to support patent expansion, IND filing, and attract pharmaceutical partnerships.
- Broaden platform potential by adapting PDLE for delivery of diverse therapeutic cargos.

Population to be served

- Pediatric patients with neuroblastoma, which often resists immune checkpoint inhibitors.
- Adult patients with triple-negative breast cancer (TNBC), an aggressive and immune-resistant subtype.
- Broader cancer populations in Florida, especially those with PD-L1-expressing tumors.
- Underserved and immune-resistant cancer populations, by offering a less toxic, targeted therapeutic alternative.

Research methods or project implementation plan

- Phase 1: In Vitro Studies (Months 1–4)
  - Use 2D and 3D cell culture models of neuroblastoma and TNBC.
  - Evaluate PDLE, PDLE-S3, and combinations with carboplatin.
  - Assess cell viability, apoptosis, and optimal dosing.
  - Analyze PD-L1, STAT3, and immunosuppressive markers via western blotting.
- Phase 2: In Vivo Studies (Months 5–10)
  - Use NCG-HIL15 humanized mice with cancer xenografts.
  - Administer PDLE-S3 alone and with carboplatin.
  - Monitor tumor growth, immune activation, and survival.
  - Conduct single-cell RNA sequencing, proteomics, and flow cytometry.
- Phase 3: Toxicity and Safety Assessments (Months 8–12)
  - Evaluate pulmonary, hepatic, and gastrointestinal toxicity via histology and biomarkers.
  - Use fecal markers (zonulin, calprotectin) for GI toxicity.
  - Perform immune profiling with cytokine assays and flow cytometry.
- Additional Components
  - Use SynergyFinder 3.0 for drug synergy analysis.
  - Prepare for IND application and patent expansion.
  - Engage with industry partners for commercialization.

Project Title: Cancer Disease and Clinical Trials Education
Principal Investigator: Jon DuBois
Institution: Jupiter Medical Center, Anderson Family Cancer Institute
Funding: $266,766.00
Cancer types: Lung, Breast, Colon, Prostate, Gynecologic

Goals or projected outcomes

- Provide a comprehensive, structured patient education framework to address the gap in education for newly diagnosed and recently relapsed cancer patients.
- Empower patients with essential knowledge about their specific cancer, diagnostic process, staging, treatment options, and clinical trials.
- Enhance patient engagement and improve communication with treatment teams.
- Encourage informed decision-making and increase awareness/participation in clinical trials.
- Reduce confusion, fear, and uncertainty at diagnosis by helping patients know what questions to ask.
- Contribute to speeding up research participation by improving patient education about trials (as stated in the application's innovation description).

Population to be served

- Cancer patients in Florida—specifically newly diagnosed and recently relapsed patients—served by Jupiter Medical Center's Anderson Family Cancer Institute.

Research methods or project implementation plan

- Approach/design
    - Implement a structured education framework delivered by physicians and trained clinical research personnel.
    - Conduct open-forum sessions providing a primer on cancer type, diagnostics, staging, treatment options, and clinical trials, with time for patient questions.
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Best Practices.
    - Research type: Patient and Family Support.
    - Access to patient support networks: Yes.
    - Methods to measure patient/family engagement: Yes.
    - Patient engagement/support mechanisms: Implemented immediately.
    - Partnerships to access/share best practices: Established in less than 3 months.

Project Title: Discovery of marine natural product antagonists of Ewing Sarcoma target as Novel Therapies
Principal Investigator: Kirstie Francis
Institution: Mote Marine Laboratory
Funding: $230,578.00
Cancer type: Bone

Goals or projected outcomes

- Optimize a high-throughput Differential Scanning Fluorimetry (DSF) assay to detect compounds that bind EWS-FLI1 mRNA.
- Screen 500 pre-fractionated marine microbial extracts to identify hits that interact with EWS-FLI1 mRNA.
- Purify active compound(s) and demonstrate activity in Ewing Sarcoma (ES) cell lines, including:
    - Tumor-cell killing (cytotoxicity against ES cells)
    - Impact on protein levels and functions critical to cancer cell signaling
- Produce lead candidates and mechanistic evidence supporting development of first-in-class therapeutics against EWS-FLI1 (a target with no current FDA-approved direct inhibitors).

Population to be served

- Children and adolescents with Ewing Sarcoma (rare pediatric cancer)

Research methods or project implementation plan

- Assay development: Optimize a DSF biophysical assay specifically for EWS-FLI1 mRNA to enable high-throughput detection of ligand binding.
- Primary screen: Test 500 pre-fractionated marine microbial extracts to identify EWS-FLI1 mRNA binders.
- Hit purification: Isolate and purify active compound(s) from extracts showing DSF activity.
- Cell-based validation:
    - Evaluate purified compounds in ES cell lines for cytotoxicity (ability to kill ES cells).
    - Assess effects on protein levels and functions central to cancer cell signaling, to understand mechanism(s) of action.
- Advancement criteria: Integrate DSF binding, purification, and cellular/functional data to determine which compounds are promising drug leads for ES.

Project Title: Investigating the efficacy of Dexamethasone plus conventional hypomethylating agent plus BCL-2 Inhibitor in the Treatment of Acute Myelogenous leukemia (AML)
Principal Investigator: Gustavo Rivero
Institution: TGH Cancer Institute
Funding: $96,800.00
Cancer type: Blood

Goals or projected outcomes:

- Improve clinical efficacy in elderly AML by adding dexamethasone to HMA + BCL-2 inhibitor (two induction cycles).
- Increase complete remission (CR) rates and event-free survival by:
    - Selectively eliminating RAS-mutant and high-risk MDS-related clones.
    - Mitigating leukemia NF-κB–mediated inflammatory survival pathways.
- Identify predictive biomarkers of response, including cytokines (IL-6, IL-1β, TNF-α), variant allele frequency (VAF) dynamics in RAS/MDS-related mutations, and NF-κB network gene expression changes.
- Generate a data package to justify future combinational trials with targeted agents (e.g., FLT3, IDH1/2 inhibitors, venetoclax).

Population to be served:

- Elderly patients (age >60) with acute myelogenous leukemia (AML) receiving induction therapy.
- Florida-based implementation

Research methods or project implementation plan:

- Study design and treatment
    - Single-arm treatment of elderly AML with HMA + BCL-2 inhibitor plus adjuvant dexamethasone for two cycles.
    - Clinical response assessment: CR evaluation on Day 28.
- Biomarker/mechanism objectives
    - Cytokines: Measure pre/post bone marrow serum levels (ELISA) of IL-6, IL-1β, TNF-α to predict CR.
    - Genomics: Use next-generation sequencing (RNA and DNA) to:
        - Detect dexamethasone's effect on eradicating RAS and high-risk MDS-related mutations.
        - Annotate VAF changes in RAS/MDS-related mutations and correlate with CR.
    - NF-κB regulatory network: Assess pre/post dexamethasone stem/progenitor cell gene expression (targets include IL-6, IL-1β, TNF, BCL-XL, BCL2, GM-CSF, G-CSF, IL-17α) and relate to CR.
- Project structure and readiness
    - Grant category: Pilot Grant; Research category: Innovation; Research type: Treatment Studies.
    - Access to required innovative technologies/resources: Yes; partnerships within <3 months.
    - Anticipated reporting of treatment efficacy: Within 6 months of study start.

Appendix 3. Progress Reports

Project Title: Florida Partnership for Adding Social Context to Address Cancer Survivorship Outcomes (ASCENT)
Principal Investigator: Dejana Braithwaite
Institution: University of Florida
Funding: $598,993.00
Cancer types: Colon, Gynecologic

Progress Report

Participant enrollment for Phase 1 has not yet begun due to delays in receiving required approvals. However, we have made significant progress toward launching the study. SRMC and IRB approvals have been obtained, and we are cleared to begin recruitment, which is scheduled to launch in early October. Other study preparations have been completed, including finalization of study materials (e.g., recruitment flyers, questionnaires, and interview guides), identification and set up of the study visit site, and development of data collection tools. Our Redcap database is currently in the final stages of preparation and will soon be ready for production.

This project is being conducted in collaboration with the University of Miami. Their IRB submission is currently in ancillary review and is expected to be ready for full committee review by the end of October. To ensure alignment across sites and maintain project momentum, we have established bi-weekly team meetings focused on coordination and standardization.

We remain committed to achieving the project objectives and are on track to proceed as planned. As part of our efforts, we will host a study launch event on Thursday, October 2, to formally announce the study and engage key stakeholders.

Project Title: Developing a biodegradable stent to protect patients from post-surgical anastomotic leaks (AL) following rectal cancer surgery
Principal Investigator: Scott Kelley
Institution: SafeGuard Surgical, Inc.
Funding: $1,994,665.00
Cancer type: Colon

Progress Report

Colorectal cancer is the third most prevalent cancer worldwide, and a surgical leak after the cancer resection remains one of its most devastating and costly complications. To mitigate this risk, surgeons often create a temporary diverting stoma, also known as a colostomy bag. While effective, this practice carries its own morbidity, cost, and quality-of-life burden, and necessitates a second operation for reversal. SafeGuard Surgical developed the LeakGuard, a biodegradable stent engineered to cover and protect the surgical site from leaks during the critical healing window. LeakGuard has the potential to save lives, reduce healthcare costs, and transform the standard of care for colon cancer. The FDA has recognized this innovative technology with Breakthrough Device designation, underscoring its potential to save lives.

Our long-term goal is to complete the necessary preclinical development and regulatory steps to support first-in-human clinical testing and a Class II De Novo submission. To achieve this, we proposed three specific aims:

- Aim 1: Perform bench testing to evaluate mechanical properties, stability, and degradation kinetics of the biodegradable stent.
- Aim 2: Conduct large-animal (porcine) studies to confirm performance in vivo and demonstrate protection against anastomotic leakage.
- Aim 3: Complete comprehensive biocompatibility testing to confirm safety.

We have made strong progress on Aim 1. Our team has successfully developed a working prototype that has undergone extensive benchtop evaluation. Initial testing confirmed adequate radial force and flexibility. Subsequent design iterations have focused on optimizing degradation kinetics, ensuring the stent provides reliable protection throughout the 2–3 week healing phase, while ultimately resorbing without the need for removal. We have also made progress on sterilization methods, manufacturing techniques and packaging—steps that are essential not only for performance but also for future scalability and commercial manufacturing consistency, all essential for FDA approval.

Parallel to this work, we have conducted preliminary large-animal studies (using pigs, since the colonic anatomy is most similar to humans) that informed design refinements and confirmed the feasibility of intraluminal placement. These early results successfully support our translational pathway and will guide protocol development for the formal animal trials planned under Aim 2. These studies will directly assess LeakGuard’s ability to prevent leakage, directly saving lives and money. Preparations for Aim 3 are also underway. We are aligning our testing plan with ISO 10993 biocompatibility standards, ensuring that evaluations of cytotoxicity, sensitization, genotoxicity, and systemic toxicity are rigorous and sufficient to support FDA requirements.

In summary, we have achieved significant milestones toward our stated objectives. LeakGuard has advanced from concept to a functional, testable prototype; the bench-testing has validated core performance attributes; and preliminary in vivo work has provided critical design refinements to transition to Aim 2. We are now focused on finalizing Aim 1, preparing for porcine

studies in Aim 2, and establishing the biocompatibility testing framework for Aim 3. Together, these efforts are moving us efficiently toward first-in-human clinical evaluation of a device that holds the potential to fundamentally reduce the morbidity, mortality and their inherent costs associated with colorectal cancer surgery.

Project Title: Mitigation of Chemotherapy-induced Nephrotoxicity via Podocyte Protection
Principal Investigator: Darlah Lopez
Institution: 149 BIO, LLC
Funding: $941,944.00
Cancer type: Other (Special) – Kidney damage associated with cancer treatment

Progress Report

Many cancer treatments—including commonly used chemotherapy drugs like Adriamycin and cisplatin, as well as newer targeted and immune therapies—can cause serious kidney damage. This damage often shows up as acute kidney injury, chronic kidney disease, or protein leakage in the urine. A major reason for this injury is the loss of podocytes, the specialized cells in the kidney that act as a key part of its filtration barrier. When podocytes are damaged and lost, the kidney can no longer filter blood properly, leading to worsening disease.

Right now, there are no therapies that directly protect podocytes from this type of injury. Our project is focused on developing a new type of treatment: highly specific antibodies that activate VLA3, an important protein that helps podocytes stay anchored in place. By supporting VLA3, we hope to keep podocytes stable and prevent the chain reaction of injury that leads to kidney disease.

To do this, we are using advanced screening technology combined with artificial intelligence to design and refine small antibody fragments. This approach allows us to improve their strength, accuracy, and safety—ensuring that they bind to VLA3 while avoiding similar proteins. This award supports our mission to create a new class of kidney-protective therapies that safeguard kidney health, giving cancer patients a better chance to avoid long-term complications.

Project Title: Exosome Interception: A New Strategy to Stop Breast Cancer Metastasis
Principal Investigator: Annette Khaled
Institution: University of Central Florida
Funding: $257,948.00
Cancer type: Breast

Progress Report

Breast cancer (BC) is the most diagnosed cancer in women and a significant cause of death in men. BC can be fatal when it recurs and spreads or metastasizes to different sites in the body, such as the lungs or liver. A new approach is needed to stop the growth and spread of lethal BC. This project focuses on small nano-sized particles released by BC cells called exosomes or extracellular vesicles (EVs). Exosomes or EVs are miniaturized versions of cells with a surrounding protective membrane containing the same proteins and nucleic acids found in cancer cells. When EVs from cancer cells are taken up by normal cells in the liver, lungs, or brain, they fundamentally alter these cells, creating a hospitable environment for circulating tumor cells to form new tumors. A drug that prevents the production of EVs from cancer cells could stop this process and keep BC from growing and spreading. To develop effective inhibitors specific to cancer EVs, new knowledge on how cancer EVs are formed is needed. This information could lead to new best practices for stopping BC cells from growing and spreading, improving the survival of BC patients.

One of the first steps to making EVs is to synthesize proteins that support EV production. The research team and others discovered that a protein-folding complex, known as a chaperonin (CCT or TRiC for short), is essential for proteins from cancer cells to acquire their functional properties. In this project, researchers are studying a new activity for CCT: to produce exosomes or EVs from BC cells that enable the cancer to spread. Findings could reveal for the first time how cancer EVs are made and differ from non-cancer EVs. Current progress in the project's first specific aim involves examining the role of CCT in the selective loading of EV cargo. Initial work revealed that when CCT increases in BC cells, fewer total EVs are made, but these EVs contain high levels of CCT. Conversely, when CCT is depleted in BC cells, more EVs are made, but these lack CCT. These findings revealed that CCT is dynamically manipulating EV synthesis and selective cargo loading. This discovery positions the research team to test a new therapeutic, developed in the lab, called Z-TOP (Zwitterion-TRiC OFF Peptide), which specifically binds to and inhibits CCT, potentially stopping the production and release of BC EVs.

These studies could yield a new approach to curing BC, using Z-TOP to stop the release of cancer-causing EVs. Treatments for BC, such as chemotherapies, may increase rather than hinder the release of metastasis-promoting EVs, and the available EV-inhibiting drugs target all EVs (good and bad). By only stopping the cancer-derived EVs through inhibiting CCT, Z-TOP, as an adjuvant therapy, could prevent cancer recurrence and metastasis in patients with the most common forms of BC by stopping the release of EVs that could seed future metastatic sites, thereby inhibiting the growth and spread of lethal BC.

Project Title: Make FDA-Approved Anticancer Drugs Effective for the Most Difficult-to-Treat Breast Cancer Patients by Targeting a Novel Drug-Resistant Cancer Gene Using Innovative Drug-Delivery Technologies
Principal Investigator: Jihe Zhao
Institution: University of Central Florida
Funding: $510,656.00
Cancer type: Breast

Progress Report

The research team had well been planning while excitedly waiting for the grant agreement to be officially finalized. Immediately after the grant agreement between the Florida Department of Health and the University of Central Florida Board of Trustees was reached in late July, the research team started the engine for the bench work to implement and execute the research experiments proposed for the project. Specifically, the research team has already begun the cell culture of the most difficult to treat, drug resistant human triple negative breast cancer cells proposed in the project specific aim

1. The research team has also obtained the umbilical and bone marrow-derived human mesenchymal stem cells and their culture media and reagents for producing and collecting the exosomes for the cancer cells selective loading and delivery of the drug-resistant cancer gene targeted antibody drug available in the labs of the research team and the FDA-approved chemotherapeutic anticancer drugs. Once the loading and delivery conditions are optimized, the research team will begin to test the effectiveness of the optimized conditions on killing the human triple negative breast cancer cells both in vitro proposed in the project specific aim 1 and in vivo proposed in the project specific aim.
2. In the meantime, the research team will optimize the cancer cell selective drug loading and delivery conditions similarly for the murine triple negative breast cancer cells proposed, and test the killing effect of the FDA-approved chemotherapeutic anticancer drug both in vitro proposed in the project specific aim 1 and in vivo proposed in the project specific aim 3 as well as of the FDA-approved immune therapeutic anticancer drugs in vivo proposed in the project specific aim.
3. Customized manufacturing and delivery of the immune therapeutic drugs have already been consulted and planned with the collaborative commercial vendor. In summary, the project’s engine is running well and hopefully all the experiments will go smoothly.

Project Title: GOALHealth: Geriatric Oncology Adherence Link: Testing an Established Prototype to Support Older Adults Prescribed Oral Anticancer Medication
Principal Investigator: Victoria Marshall
Institution: University of South Florida
Funding: $213,219.00
Cancer type: Other (Special) – Geriatric adults prescribed an oral anticancer medication

Progress Report

This grant was recently executed. We are currently finalizing the contract between the University of South Florida and Geekbears, our external web developer. The kickoff meeting between Geekbears and the Dr. Victoria Marshall (PI) is scheduled for Thursday, October 2. In preparation for this meeting, the symptom management toolkits and drug information sheets have been reviewed by undergraduate research assistants and Dr. Marshall to ensure accuracy, readability (goal of 6th grade reading level), and completeness.

Project Title: Reducing Cancer Health Disparities in Florida through Functional Precision Medicine and Artificial Intelligence - Pilot Study serving Minority, Underserved Cancer Patients.
Principal Investigator: Noah Berlow
Institution: First Ascent Biomedical
Funding: $2,000,000.00
Cancer type: Other (Special) – Precision Medicine

Progress Report

Regulatory Progress
At the request of the Florida Department of Health (DOH), we began the Institutional Review Board (IRB) process, which is required to make sure all clinical activities are safe and ethical. Our first submission was completed shortly after the DOH request. After receiving feedback from the IRB, we quickly re-submitted the updated application. We expect final approval as early as next week, which will allow us to officially start enrolling participants under an IRB. This approval is an important step, moving the clinical program from planning to action. Importantly, this IRB is designed so that cancer patients of any age, with any type of cancer, and from any clinical site in Florida, can join the study. This ensures that physicians and patients across the state will have access to personalized treatment options. We also created the official study entry on ClinicalTrials.gov (NCT07167381). This public database shares study details with patients, families, and doctors, and helps raise awareness across Florida. It also ensures the study meets national standards for transparency and provides a trusted source of information for anyone who wants to learn more.

Laboratory Readiness
The clinical laboratory supporting the program is now ready for both blood cancers and solid tumors. This means the lab's methods have been confirmed to be accurate and reliable, producing consistent results across patient samples. Validation also shows that the lab can handle the expected testing volume and provide results on time. With trained staff and quality checks in place, the lab is ready to begin testing as soon as patient enrollment starts.
This readiness goes beyond just having the equipment in place. It gives doctors confidence that results are accurate, ensures patients and families can trust the testing process, and allows the program to grow smoothly as more patients join. By preparing the lab ahead of time, we have reduced the risk of delays and built a strong foundation for the program. We have also processed our first solid tumor sample from a Florida-based cancer patient (under CLIA, not under the IRB) with colorectal cancer, and returned data within the timeframe required to support clinical decision-making, demonstrating the first success of the Florida Fund study to support individualized treatments for cancer patients.

Community Engagement
We have started connecting with oncologists and leaders at major cancer centers, including Moffitt Cancer Center, University of Miami Sylvester Cancer Center, Miami Cancer Institute, Nicklaus Children's Hospital, and Nemours Children's Hospital. These discussions have helped raise awareness of the program and prepare cancer patients across the state for participation once the IRB is approved. By starting these partnerships early, we are setting the stage for strong collaboration and steady patient referrals for both adult and pediatric patients. Working with these respected institutions also allows us to learn from their experience and make the program fit smoothly into existing clinical practices. These conversations have been very encouraging and show strong interest from providers in expanding access to cancer research across Florida.

Project Title: A Multimodal Lung Cancer Risk Assessment Model using Comprehensive Data Integration
Principal Investigator: Nezamoddin Kachouie
Institution: Florida Institute of Technology
Funding: $422,453.00
Cancer type: Lung

Progress Report

Initial phase of the Multimodal Lung Cancer Risk Assessment Model project has focused on assembling the right expertise, exploring available data, and developing initial models to better understand the challenges of predicting patient outcomes in lung cancer. These early efforts have taken time, but they form an essential foundation for building an accurate and patient-centered risk assessment system that goes beyond what traditional clinical staging can provide.

Team Formation and Recruitment
We began by strengthening the project team with the recruitment of postdoctoral researchers specializing in computer science, data science, and statistics. Graduate students have also joined, contributing skills in programming, data analysis, and medical imaging. This diverse team ensures that machine learning expertise, statistical modeling, and medical image processing knowledge are integrated into every stage of development. The combination of postdoctoral leadership and student support provides both innovation and capacity for large-scale data analysis.

Identifying Data Bases
A major focus has been identifying and cataloging data repositories that can support the development of robust risk models. These include available electronic tabular records, imaging databases, genomic resources, and behavioral datasets. Large cancer research repositories are being reviewed as potential sources. Each source has limited collection of patients' factors. Different data sources offer complementary perspectives, such as genetic information, imaging biomarkers, and clinical outcomes, that together provide the multimodal data needed to capture the complexity of lung cancer risk.

Developing Preliminary Models
As part of initial phase, the team has begun developing preliminary risk models based on clinical staging, which is the current standard in assessing lung cancer outcomes. These models demonstrated the limitations of relying solely on clinical stage, as they often fail to capture the full complexity of disease progression or individual patient variability. While staging provides a broad categorization, it overlooks critical differences driven by genetics, imaging features, lifestyle factors, and treatment history.

Identifying the Shortcomings of Clinical Staging
Our preliminary results confirm that clinical stage alone is insufficient for predicting survival or tailoring treatment recommendations. Two patients with the same stage may experience vastly different outcomes due to underlying biological, behavioral, or environmental factors. This underscores the urgent need for more holistic and customized risk measures that can integrate multiple data sources to better reflect each patient's unique risk profile.

Toward a Multimodal Approach
To address these shortcomings, the team has been working to identify key features across different modalities that can contribute to more accurate risk prediction. These include radiomic

signatures from imaging, genetic mutations, laboratory biomarkers, lifestyle factors such as smoking history, and demographic variables. Integrating these features into a unified predictive framework promises to deliver a more personalized and dynamic risk assessment tool for lung cancer patients.

Conclusion

The tasks in the initial phase are essential for establishing a solid foundation. Recruiting the right team, identifying data sources, testing preliminary models, and evaluating the limitations of clinical staging have clarified the path forward. These efforts lay the groundwork for building a multimodal, AI-driven risk assessment system that will provide more accurate, individualized, and actionable insights for patients and clinicians, ultimately improving care and outcomes in lung cancer.

Project Title: Characterization of probiotic Lactobacillus spp. and their metabolites as a novel therapeutic for esophageal adenocarcinoma in innovative pre-clinical model systems
Principal Investigator: Claudia Andl
Institution: University of Central Florida
Funding: $380,272.00
Cancer type: Throat

Progress Report

Gastroesophageal reflux disease (GERD) arises when acidic gastric contents reflux into the esophagus. This chronic condition damages the esophageal lining, resulting in irritation and the characteristic symptom of heartburn. Approximately 20% of the U.S. population is affected by GERD. Alarmingly, despite available standard therapies, there has been a reported 50% increase in the incidence of Barrett's esophagus—a precancerous lesion associated with GERD—among middle-aged adults (45–64 years) in Florida.

The specific aim of this study is twofold: (1) to develop novel preclinical models capable of identifying Lactobacillus-derived products that mediate protective functions in esophageal tissue, and (2) to evaluate these bioactive compounds for their potential in cancer prevention and treatment.

(1) To expand our repertoire of clinically relevant preclinical models, we proposed the use of patient-derived, three-dimensional (3D) organoid models to identify bioactive components of probiotic Lactobacillus spp. with potential application as novel therapies for esophageal adenocarcinoma. Progress in this area was initially delayed due to administrative challenges with the subaward to Columbia University, where our collaborators isolate and generate patient-derived organoids. To address this limitation, we in the meantime developed new approaches by establishing 3D culture systems using human Barrett's esophagus cell lines and murine esophageal tissues. We further validated these models by administering live Lactobacillus spp., successfully demonstrating bacterial interaction with the cultures. We are now investigating disease-associated molecular signatures and their modulation in response to probiotic treatment. Given the scarcity of robust models for esophageal adenocarcinoma, this represents a significant milestone that establishes feasibility and provides critical tools for testing innovative therapeutic strategies.

(2) We also proposed to identify novel secreted probiotic bacterial compounds, which could become promising new therapeutics. To evaluate these bioactive compounds for their potential in cancer prevention and treatment, we need to enrich and isolate them from bacterial growth media. To this end, we have successfully established protocols for extracting and enriching both soluble and insoluble bacterial products. Importantly, these methods are compatible with our culture systems and do not compromise cell viability. Current efforts are focused on assessing which bacterial fractions confer protective effects in cell culture models. These candidate fractions will next be tested in animal models of esophageal disease, followed by biochemical characterization of active compounds using mass spectrometry.

In summary, we have made timely and substantive progress in advancing the development of preclinical models of esophageal disease. Development of these new models will allow us to address critical barriers in current treatments for esophageal adenocarcinoma as they will serve as essentials platform for identifying and testing new therapeutic agents. Ultimately, the

outcomes of this project have the potential to benefit the large and growing population of patients with GERD who are at elevated risk for esophageal adenocarcinoma.
Project Title: A Chemotherapy-free Treatment Regimen for HER-2 Positive Breast Cancer utilizing HER2-directed Intratumoral Dendritic Cell Immunotherapy plus Trastuzumab and Pertuzumab
Principal Investigator: Hyo Han
Institution: H. Lee Moffitt Cancer Center & Research Institute, Inc.
Funding: $1,429,728.00
Cancer type: Breast

Progress Report

The clinical trial was activated to accrue patients on 8/20/2025. The first patient signed the consent on 8/26/2025 and initiated the study treatment on 9/17/2025. We are currently in the active recruitment phase and continue to screen and enroll eligible participants.

Project Title: Advancing Personalized Ion Radiation Therapy: Integrating Cellular Pathomics and Relative Biological Effectiveness Modeling for Improved Cancer Outcomes in Florida.
Principal Investigator: Chris Beltran
Institution: Mayo Clinic
Funding: $946,965.00
Cancer type: Pancreatic, Brain

Progress Report

The funding started on September 1st. Since then, we have purchased all of the cell lines for analysis and have started culturing the first 2 cell types for analysis. We have started DNA and Nuclei isolation for Pancreas and V79. The AI training for rapid morphology quantification has also started for the above two cell lines.

Project Title: Pre-clinical studies of splicecosomal immunomodulators in combination with checkpoint inhibitors in humanized melanoma mouse model
Principal Investigator: Dmitriy Minond
Institution: Nova Southern University
Funding: $424,289.00
Cancer type: Skin

Progress Report

Following recent execution of the contract, we proceeded to synthesize the anti-melanoma compounds for the study. Additionally, we are working with the vendors of humanized mice to develop a study protocol and delivery schedule, as these mice require 2-3 months for "humanization" and tumor implantation before the studies can begin.

Project Title: Development of Genetically Engineered Smart Exosomes for Targeted Treatment of Cancer
Principal Investigator: Mandip Sachdeva
Institution: Florida A&M
Funding: $281,879.00
Cancer type: Breast, Pediatric

Progress Report

The funds for this project came a bit late and it took some time to set up the account. Now since everything is setup, efforts are being made to recruit the personnel for this project. Also supplies are being arranged and cell lines required for the project are also being procured. Currently we are growing resistant MDA-MB231 cells and also SF 188 brain tumor cells. There were some problems of contamination initially which we have overcome now. The next report most likely we will have some more research experimental data.

Project Title: A Retrospective Review and Cross-Platform Comparison of ctDNA Results for Standardization, Clinical Validation, and Application in Cancer Monitoring.
Principal Investigator: Oleg Gligich
Institution: Mount Sinai Medical Center
Funding: $156,300.00
Cancer types: Lung, Breast, Colon, Prostate, Bladder

Progress Report

Under the leadership of Dr. Oleg Gligich, our research program has made significant strides in establishing the infrastructure and initiating data collection for our ctDNA-based oncology study. In July and August, we conducted a thorough candidate selection process for the Clinical Research Associate role. This culminated in the onboarding of a PhD-trained biomedical scientist in September, bringing expertise in molecular biology, translational oncology research, and data analysis to the team.

Since onboarding, we have begun collecting circulating tumor DNA (ctDNA) results from the Signatera platform (Natera) and are actively building a longitudinal database that compares ctDNA profiles with disease progression, benchmarked against gold-standard imaging modalities such as PET and CT scans. We have also initiated collaborations with representatives from Guardant and Tempus to gain access to their portals, enabling data collection from oncology clinicians across the Mt. Sinai network. Our goal is to compile ctDNA results from three major platforms—Signatera, Guardant, and Tempus/Personalis —spanning the past four years. This effort involves collaboration with industry partners, academic research departments, and oncology practices throughout Florida. Dedicated data specialists are managing the extraction and organization of this information to ensure consistency and accuracy across platforms. The expected deliverable is a comprehensive, anonymized dataset that includes ctDNA results, patient demographics, treatment regimens, and clinical outcomes. This dataset will support cross-platform comparisons and longitudinal analyses of ctDNA as a biomarker for disease progression.

Milestones Achieved: (1) Data Collection - Ongoing, with significant progress made on the Natera platform. Initial patient lists have been expanded from 80 to 120, and classification based on longitudinal ctDNA profiles is underway. (2) Data Organization: Comparative tables for platform features have been drafted. Reference banks are being built to support analysis. (3) Clinical Integration: Patient chart reviews via Epic are being conducted to confirm and enrich dataset variables. (4) Analysis Preparation: Preliminary pattern recognition and variable loading have begun, setting the stage for formal analysis.

Project Title: AI-Enhanced Biomarker-Driven Early Detection and Precision Therapies for Glioblastoma and Brain Metastasis
Principal Investigator: Atif Hussein
Institution: Memorial Healthcare System
Funding: $1,280,557.00
Cancer type: Brain, Breast

Progress Report

Our project is focused on advancing early detection and treatment strategies for glioblastoma (GBM) and brain metastases by comparing outcomes of using cerebrospinal fluid (CSF)-based ctDNA diagnostics of circulating tumor DNA. A key innovation is the integration of artificial intelligence (AI) to improve the speed and accuracy of patient screening and biomarker analysis.

Since receiving this grant award, we have successfully developed and received IRB approval for a protocol to establish a brain tumor biorepository. This resource will support the collection and long-term storage of brain tissue samples and associated clinical data, critical to the success of the project. This milestone required close coordination across neuro-oncology, pathology, and other departments, and was carried out in collaboration with our partner institution, Florida Atlantic University (FAU), under the MCI/FAU Florida Cancer Center of Excellence.
We are currently assessing available AI platforms to identify the optimal solution for model development and validation. We remain on track to meet our objective of integrating AI within the first six months of the project.

Additionally, we are collaborating with Alliance, a national clinical trials network, to initiate a Phase II trial evaluating a novel immunotherapy-chemotherapy combination for recurrent GBM, which may help establish a new standard of care. The study received IRB approval and was opened to enrollment last week. We will open the study locally at our site and plan to start enrollment as soon as possible.

Project Title: A Twin SQL and Smart Cancer Repository and Query System with Analytical Intelligence Capability and Shared Access
Principal Investigator: Nezamoddin Kachouie
Institution: Florida Institute of Technology
Funding: $600,071.00
Cancer type: Lung

Progress Report

During the initial phase of the Twin SQL and Smart Cancer Repository and Query System project, we have concentrated on the essential groundwork required to establish a scalable and robust foundation for the system. This work has centered on building the right team, assessing technological infrastructure, and carefully evaluating the strategies for implementing and maintaining a secure, efficient, and cost-effective repository. While these tasks have taken significant time and effort, they are indispensable for ensuring long-term success of any shared access repository involving sensitive clinical and research data.

Team Formation and Recruitment
A critical first milestone has been the recruitment of highly qualified team members. We have successfully hired postdoctoral researchers in computer science and data science to lead the technical development of the repository system. Graduate students have also joined the project, providing vital support in programming, data management, and statistical modeling. Together, this team brings expertise in cloud computing, cybersecurity, medical informatics, and advanced statistical learning, creating the interdisciplinary foundation necessary for this complex initiative. Establishing this mix of personnel ensures that the project integrates expertise from operations research, mathematics, computer science, and clinical oncology.

Assessment of Infrastructure and Resources
Parallel to team building, we undertook a detailed assessment of the hardware, software, and processes needed for implementation. This evaluation focused on identifying computing resources capable of supporting multimodal datasets ranging from structured patient records to unstructured imaging and genomic information. The team reviewed both on-premise server options and leading cloud platforms such as AWS and Azure, analyzing their capabilities in terms of scalability, interoperability, and compliance with privacy standards like HIPAA. The software assessment covered relational and non-relational database technologies, ETL (extract, transform, load) pipelines for data cleaning and integration, and large-language-model-based query systems designed to make the repository accessible to both technical and non-technical users.

Repository Scope and Data Sources
An important part of this project has been identifying and cataloging potential data and application repositories to feed into the system. These include imaging databases (using DICOM standards), genomic resources such as TCGA and gnomAD, and large public clinical trial repositories. Securing access to the NCI PLCO dataset, which includes more than 100,000 patient records, represents a major step toward pilot implementation. These sources provide the diversity of inputs that the repository will integrate and the interoperability challenges that must be overcome.

Conclusion
Although the initial tasks required significant planning time, they provide the essential groundwork for a scalable and secure system. Establishing the right team, assessing

infrastructure, and rigorously evaluating repository models are not optional steps but mandatory investments for ensuring that the Smart Cancer Repository will meet its goals of improving and accelerating research, and enabling collaborative discovery across institutions.

Project Title: Rapid, low-cost early detection test for lung cancer
Principal Investigator: Elizabeth Franzmann
Institution: Vigilant Laboratories
Funding: $882,198.00
Cancer type: Lung

Progress Report

Florida reports 17,276 new lung cancer cases and 10,880 deaths annually. Low-dose computed tomography (LDCT) for smokers reduces lung cancer deaths, but screening with this method occurs only 20% of the time, partly due to cost, concerns about risks, and patients' difficulty accessing it. More accessible and cost-effective screening tools are needed to improve early detection and control of this deadly disease.

Liquid biopsy offers a minimally invasive method for detecting lung cancers. Abnormal production of the body’s building blocks, which occurs in cancer, can be measured in body fluids like saliva and blood. These building blocks, including proteins and DNA, are known as biomarkers. Sampling these fluids and using tests looking for abnormal biomarker production is known as liquid biopsy. While biomarkers have been investigated for lung cancer, none have been scientifically accepted as the new standard of care. This is because the tests do not adequately detect early-stage disease, when the cancer is most likely to be cured. Other drawbacks include complexity, cost, and the time required to obtain results.

Our protein-based oral rinse method offers significant advantages over DNA-based and other tests due to its noninvasive nature, low cost, rapid results, and effectiveness in early detection. While our group has shown the benefit of a set of biomarkers for early detection of mouth and throat cancer, thanks to the generous support of the Florida Cancer Innovation Fund, we are beginning to look at the expression of these markers in lung cancer. Since the award started in July 2025, we have continued to enroll a group of patients from under-resourced areas in South Florida. These saliva test results, referred to as controls, will help us determine what the normal levels of these biomarkers are in people living in Florida neighborhoods most at risk for late-stage cancer. We can then compare these levels to those of cancer patients who are similar in age, sex, and smoking habits to the controls to identify patterns of biomarker expression in cancer patients versus controls.

So far, 169 patients have received free exams and education and provided saliva and health-related data. We have also collected saliva samples from 6 lung cancer patients and began biomarker testing in these patients. This initial work suggests that biomarker levels in lung cancer cases are higher than in the controls. To determine whether this finding is genuine and not due to chance, we are continuing our plans in a close partnership with the University of Miami, to enroll additional lung cancer cases, to collect specimens from lung cancer patients and control subjects, and to test the initial versions of the point-of-care device we are developing.

We are also conducting experiments with the University of Miami to discover new biomarkers for lung cancer. We are confident this collaboration will lead to an effective, point-of-care test for early detection of lung cancer.

Project Title: Implementation of electronic patient-reported outcomes for symptom management in cancer patients
Principal Investigator: Jennifer LeLaurin
Institution: University of Florida
Funding: $326,326.00
Cancer type: All

Progress Report

The collection of patient-reported outcomes (PROs) is an evidence-based best practice for capturing symptoms in a consistent and validated manner. Transitioning to electronic PROs (ePROs) enables patients to report symptoms remotely, giving clinicians the opportunity to detect emerging problems and intervene earlier. The objective of our research is to advance best practices for cancer symptom management in Florida by developing evidence-based, user-centered electronic health record (EHR) tools for ePRO monitoring. Specifically, we aim to: (1) build and pilot test a comprehensive collection of cancer ePRO questionnaires in the Epic EHR, and (2) co-design ePRO interfaces and workflows with patients and healthcare providers. Once developed, these resources will be shared with other health systems using Epic to serve as a foundation for broader implementation of ePRO-based cancer care.

In the first quarter of the project, we assembled a multidisciplinary team that includes oncology clinical leadership (physicians and nursing), clinic administration, Epic EHR specialists, and experts in biomedical informatics, user-centered design, implementation science, and community engagement. This diverse expertise positions the project to address both the clinical and technical challenges of ePRO integration while ensuring alignment with patient needs. This team collaborated to select a foundational ePRO system build that incorporates the National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). This initial build provides the infrastructure needed to capture patient-reported symptoms and treatment toxicities in a streamlined and validated format within Epic. Importantly, this EHR build will also serve as the basis for upcoming co-design activities under Aim 2.

In the next quarter, we will initiate patient interviews and usability testing with both patients and providers. These sessions will apply rapid qualitative and user-centered design methods to refine survey content, clinical workflows, and provider-facing dashboards. Ongoing engagement with patients, clinicians, and administrators will ensure that the resulting tools are not only evidence-based but also feasible, usable, and responsive to real-world clinical needs.

Together, these accomplishments represent meaningful progress toward our overarching goal of producing scalable, EHR-integrated ePRO resources that enhance timely cancer symptom management, improve patient outcomes, and reduce health care utilization across Florida.

Project Title: Maximizing Patient Inclusion In Genetic Biomarker Testing While Minimizing Time To Receive Results In Lung Cancer
Principal Investigator: Paul Hakimata
Institution: Memorial Healthcare System
Funding: $1,664,255.00
Cancer type: Lung

Progress Report

Overall update:

1. Obtained quotes for the various equipment and awaiting FDOH approval to purchase – needed for implementation of Aspyre Lung and liquid biopsy (LBx) NGS assays.
2. IRB protocol has been written and approved.
3. Next week we'll meet to adjust budget based on our protocol and submit to FDOH for approval.

Aim 1: Implement and Validate the Aspyre Lung Assay on Cytological Smears and LBx Samples for Rapid, Inclusive Biomarker Profiling.

1. Tested various LBx collection kits and various circulating-cell-free DNA/ circulating-cell-free RNA (ccfDNA/RNA) extraction kits.
2. Developed recipe for custom urine LBx collection kit.
3. Developed optimal protocol to collect and extract ccfDNA/RNA from plasma as well as urine.
4. Pending equipment purchases to start trial assay runs.

Aim 2: Correlate Results from Cytology Smears and Minimally Invasive Methods with Tissue-Based NGS to Ensure Equivalent Accuracy and Clinical Utility.

1. Data collection tools that need to be integrated with our laboratory information system are in development.

Aim 3: Integrate the New Workflow to Improve Patient Inclusion.

1. Potential LBx collection workflow has been developed. Awaiting implementation – pending equipment purchases.

Project Title: Feasibility of the Physical Activity and Connectivity for Testicular Cancer Survivors (PACT) program
Principal Investigator: Michael Rovito
Institution: University of Central Florida
Funding: $238,919.00
Cancer type: Testicular

Progress Report

Recruitment Progress

The study is currently in the recruitment phase, with promising progress achieved through two complementary modalities:

1. Targeted Survivor Network Engagement (word of mouth and direct outreach to known survivors)
2. Digital Community-Based Recruitment (social media campaigns and online support platforms)

To date, these strategies have resulted in the successful enrollment of TCa survivors into the intervention, with Targeted Survivor Network Engagement yielding 66% of participants and Digital Community-Based Recruitment yielding 33%. This dual approach has enabled us to balance both depth of engagement and geographic breadth, which is essential for ensuring feasibility and generalizability of the study's outcomes.

Study Rationale and Significance

TCa survivors face a constellation of long-term psychosocial and physical health challenges. Evidence suggests that physical activity (PA) can play a critical role in improving survivorship outcomes, yet the majority of existing research has focused on high-intensity exercise programs. While effective in the short term, these approaches are often undermined by issues of sustainability and participant attrition.

The current study is designed to fill this gap by evaluating the feasibility of a low-intensity, accessible, and survivor-centered PA intervention. Our approach emphasizes real-world integration of PA, aiming to foster long-term adherence while remaining sensitive to the unique needs and lived experiences of survivors.

Intervention Components

The intervention leverages two primary strategies to maximize both accessibility and adherence:

- Fitbit-Based Activity Monitoring: Participants are provided with wearable devices to objectively track PA, fostering self-awareness and reinforcing accountability.
- Structured Social Engagement: Survivors are offered online opportunities for peer interaction, designed to cultivate motivation, enhance social support, and normalize PA as a component of daily survivorship.

This combination reflects an evidence-based strategy to support both behavioral adherence and psychosocial well-being.

Preliminary Observations

While final outcomes are forthcoming, preliminary findings underscore the promise of this intervention:

- Recruitment Modality Impact: Digital recruitment yielded a more geographically diverse survivor pool, while targeted survivor outreach resulted in higher early engagement and trust in the study team.

- Participant Receptivity: Survivors are demonstrating strong receptivity to a flexible, low-intensity PA model. Feedback suggests that the paired integration of objective tracking and peer connection is particularly valuable in motivating engagement.
- Sustainability Potential: Early indications suggest that a low-intensity approach, unlike many high-intensity protocols, may better align with the lifestyle realities of long-term survivors.

Anticipated Impact
The early progress of this study highlights the feasibility of engaging TCa survivors in a scalable, sustainable intervention model. By lowering barriers to PA participation and embedding social support, this project has the potential to address long-standing limitations of high-intensity survivorship interventions.

Findings from this feasibility study will provide foundational evidence to inform larger, more definitive trials, ultimately supporting the development of tailored, survivor-centered PA interventions. This work aligns directly with the mission of the Florida Department of Health to advance evidence-based strategies that promote health, long-term wellness, and improved quality of life for cancer survivors.

Project Title: Targeting actin-microtubule network to enhance taxane efficacy in advanced prostate cancer
Principal Investigator: Michael Lu
Institution: Florida Atlantic University
Funding: $274,558.00
Cancer type: Prostate

Progress Report

Initial Quarterly Report: Project Progress (July 23 - October 1, 2025)
The project, which launched on July 23, 2025, has made strong initial progress across all three primary aims. Efforts have focused on constructing key expression vectors, initiating transcriptome studies, and developing a high-content screening platform. All work is proceeding on schedule, establishing a solid foundation for quantitative morphometric and molecular pathway analyses planned for the next quarter.

Aim 1: Cytoskeletal Expression Vectors
Progress: The GFP-Actin and GFP-tubulin expression vectors are currently under construction to support future fluorescence microscopy studies.
Accomplishments: A comprehensive collection of standardized morphometric parameters for the endogenous actin cytoskeleton has been successfully generated. This resource will be critical for lead-compound screening.
Next Steps: These new constructs will be validated under both transient and stable expression conditions in the coming weeks to confirm their utility for quantitative studies.

Aim 2: Molecular Underpinnings of PAK6
Progress: The initial phase of transcriptome studies aimed at mapping the PAK6 signaling pathway has been completed.
Current Activity: Bioinformatic analysis of the collected transcriptome data is now underway to delineate the molecular mechanisms regulating the actin-microtubule network.

Aim 3: High-Content Screening Platform
Progress: A custom analysis pipeline based on CellProfiler is being developed to create an unbiased high-content screening platform.
Quality Assurance: This platform is continuously being tested and refined with newly acquired datasets to ensure its accuracy and robustness for future screening efforts.

Outlook
The project is on track to meet its overall objectives. The next quarter will focus on validating expression vectors, completing bioinformatic analysis, and advancing the screening platform toward full operational capacity.

Project Title: Digital Biomarkers of Stress Response During and After Breast Cancer Treatment
Principal Investigator: Christian Poellabauer
Institution: Florida International University
Funding: $842,236.00
Cancer type: Breast

Progress Report

Cancer treatment is widely recognized as a significant source of psychological stress for patients. For many cancer patients, stress and other mental health problems continue long after treatment has concluded, often caused by the fear of recurrence.

The primary goal of this new project is to deepen our understanding of the relationship between cancer treatment and stress and how to detect and assess a patient's or survivor's stress response using non-invasive, continuous physiological assessments using mobile or wearable technology. In this study, we are using consumer technologies (wearables and mobile devices) to monitor the psychological wellbeing of 100 cancer patients or survivors over a period of one month each as well as 50 age-matched controls who will be monitored for one week each.

The aims of this work are:

1. to detect and quantify physiological expressions of psychological distress in cancer patients and survivors and
2. to correlate psychological symptoms with different breast cancers variants and treatment parameters. Currently, we are in the process of developing a detailed data collection protocol, recruiting personnel for the data collection, and preparing all data collection tools (e.g., purchasing and programming the wearable devices).

Project Title: Exploring the feasibility of an exercise and noninvasive brain stimulation intervention in breast cancer survivors
Principal Investigator: Ashley Artese
Institution: Florida Atlantic University
Funding: $159,626.00
Cancer type: Breast

Progress Report

The contract for our Cancer Innovation Fund was executed on August 12th, 2025. Since receiving the funds, we have been working to initiate the project and enroll participants. To work towards our goal of implementing a 4-week exercise and transcranial alternating current stimulation (Ex + tACS) in 40 breast cancer survivors, we have made the following progress:

- We have hired a graduate assistant to assist with recruitment, enrollment, data collection, and intervention implementation.
- We are purchasing necessary supplies for the project including parking passes, tACS devices, participant incentives, and exercise equipment.
- The research team (Dr. Artese, Dr. Sang Hong, Dr. Yoon, graduate research assistant, and research students) met with our consultant (Dr. James Root) to review the protocol and gain his input and training related to procedures for the neuropsychological assessments and non-invasive brain stimulation.
- The research team has practiced and trained on all assessment, exercise, and tACS procedures. Pilot testing is underway with 3 practice pilot participants who are currently completing the protocol to ensure consistency in study workflow and data collection tools along with standardization across study procedures, assessments, and intervention fidelity protocols.
- We have begun participant recruitment and plan to enroll our first participant in October 2025, with the goal of recruiting an average of 5 participants per month to achieve our goal of 40 participants within the grant award period.

We currently do not have recommendations for new best practices but will have recommendations for clinical care based on our findings at the completion of this project.

Project Title: Cancer CARE Beyond Walls – A Pilot Clinical Trial to Evaluate Administration of Cancer Directed Therapy in the Home Versus in Clinic for Patients Residing in the Florida Panhandle and Surrounding Are
Principal Investigator: Roxana Dronca
Institution: Mayo Clinic
Funding: $1,867,284.00
Cancer types: Lung, Breast, Colon, Prostate, Skin

Progress Report

The Cancer Care Beyond Walls (CCBW) Florida Panhandle Project, supported by the Florida Innovation Fund, was created to address the unique challenges patients residing in rural and remote areas face in accessing timely cancer treatment. Long travel distances to major cancer centers can be physically, emotionally, and financially burdensome, often delaying care or causing patients to miss critical appointments. This project seeks to change that by bringing cancer-directed therapies directly into patients' homes or nearby communities, eliminating the need to travel long distances. Since receiving the grant, the study protocol has been fully written, reviewed and endorsed by Mayo Clinic's disease-specific working group and was submitted to the Protocol Review and Monitoring Committee (PRMC). Final trial documents are in development, with full study activation expected by the end of 2025. Eligible participants are already being identified across the Florida Panhandle.

In parallel, major logistical infrastructure is now being set in place. A fully equipped mobile care unit has been acquired and is operational, enabling outreach to patients residing in areas possibly not covered by home health agencies. This mobile unit expands the project's reach and flexibility, with the goal of meeting patients where they are. Simultaneous to the mobile unit, we are also sourcing partnerships with various home health agencies servicing the Florida Panhandle. Patients will be offered the option to receive treatment either at home or in the mobile unit, after an initial evaluation in the clinic.

Several key innovations have emerged as part of this effort to make care more personalized, accessible, and safe. Patients will be able to choose whether they receive their treatment at home or in the mobile unit, depending on what best suits their needs. To capture the patient voice, surveys have been developed to understand their comfort level, convenience, and perceptions of safety across all care settings. The study will also assess the financial and time burden of traditional clinic-based care versus receiving treatment closer to home, shedding light on hidden costs patients often bear. Importantly, patients will be monitored by Mayo Clinic's virtual command center using Bluetooth-enabled devices, video visits, and real-time communication with oncology nurses, ensuring continuity of care and rapid clinical response when needed.

These innovations not only aim to improve the experience and outcomes for individual patients, but also to create a scalable model that can be expanded across Florida and beyond. The overarching goal is bringing high-quality cancer care to patients where they live.

Project Title: Promoting HPV Self-Testing in Primary Care
Principal Investigator: Usha Menon
Institution: University of South Florida
Funding: $729,391.00
Cancer type: Gynecologic (Cervical)

Progress Report

The grant began September 5, 2025. We are completing the final changes requested to the IRB application, setting up protocols at each clinic, and hiring a patient navigator. To date we have 18 applicants for the navigator position Interviews and final hire will be completed in the next two weeks. We also completed the contract with ROCHE to purchase the HPV testing machine. Training of staff to use the machine and conduct HPV tests are ongoing. All educational materials, consents, and surveys have been developed.

Project Title: Comparison of Cone Beam Breast CT with digital breast Tomosynthesis and contrast-enhanced breast MRI
Principal Investigator: Stuart Kaplan
Institution: Mount Sinai Medical Center
Funding: $600,000.00
Cancer type: Breast

Progress Report

Our study underwent IRB review and received IRB approval on 7/7/25. A consent form was developed and also received IRB approval. The Koning Breast CT scanner was purchased for use in the study and was installed in our Cancer Center in September 2025. The radiologists that will interpret the CT images underwent technical and clinical training in interpretation of the CT images and were awarded certificates of training. The technologists that will perform the exams were trained in the technical aspects of acquiring the images and in obtaining IV access for contrast administration.

The first patient in the study was scanned on 9/16/25. We have subsequently enrolled and scanned 4 additional patients, with many additional patients scheduled or pending scheduling for the exam in the upcoming weeks. There have been no clinical or technical complications related to the study thus far.

Project Title: Investigating the efficacy of Dexamethasone plus conventional hypomethylating agent plus BCL-2 inhibitor in the treatment of acute myelogenous leukemia (AML).
Principal Investigator: Gustavo Rivero
Institution: TGH Cancer Institute
Funding: $96,800.00
Cancer type: Blood

Progress Report

IRB via University of Florida was submitted 2 weeks ago. We are currently waiting feedback from IRB team regarding trial protocol and informed consent. We have requested laboratory material including:

a) Thermo Fisher cytokine kits
b) lab tubes for cytokines
c) kit for GTC sequencing and gene expression analysis.

We recently hire research associate who will be participating in data analysis. We expect to initiate trial accrual in about 2-3 weeks. Pre-specified endpoint analysis was rediscussed with statistician to ensure quick results. We expect to enroll 30 patients (accounting for 10% drop off rate). Interim analysis for first 10 patients should be completed by December 1st, 2025.

Project Title: Artificial Intelligence-Driven Support for Distress Management in Patients with Cancer
Principal Investigator: Zeina Nahleh
Institution: Cleveland Clinic Florida
Funding: $142,784.00
Cancer type: Other (Special) – All types of cancer on stage I, II and III, currently undergoing treatment at Maroone Cancer Center, Cleveland Clinic Florida.

Progress Report

Since receiving the Florida Cancer Innovation Fund grant, we have made steady progress toward initiating our study as outlined in the original application. Our primary objective is to evaluate the feasibility and impact of an AI-driven chatbot intervention (WYSA) as a supportive tool for cancer patients experiencing psychological distress.

At this stage, the study has been reviewed by the Peer Review Monitoring Committee (PRMC) and has gained approval. The study has also received the Cybersecurity approval #1440 from the CCF Cybersecurity Department. We are finalizing the contractual agreements with WYSA to ensure a clear framework for collaboration.

Additionally, we have conditional approval with the Institutional Review Board (IRB) and now awaiting final approval. The protocol has been developed to align with the study's objectives and ethical requirements, and IRB review is ongoing. Securing approval is a key milestone that will enable us to begin participant recruitment formally.

We have also taken critical logistical steps in preparation for the study's initiation. A REDCap database has been built to facilitate standardized and secure data collection. This database has been tailored to capture demographics, outcome measures, and engagement metrics relevant to our study endpoints. Additionally, study personnel are completing all required training to ensure the consistent implementation of study procedures, data management, and patient interactions.

The upcoming milestones will include executing the contract with WYSA, receiving IRB approval, and initiating patient recruitment.

Project Title: Targeting Lipid Signaling in Refractory and Aggressive Cancers
Principal Investigator: Jun Zhao
Institution: Cleveland Clinic Florida
Funding: $571,582.00
Cancer types: Non-Hodgkins Lymphoma, Breast, Brain

Progress Report

Aim 1.1. Synthesis of novel compounds via design.
We have employed traditional medicinal chemistry as well as structure-based design approaches to conduct structural-activity relationship study while keeping the 2-aminopyridine which is essential to bind the ATP binding site. We have designed a series of new compounds to potentially improve solubility and bioavailability based on our latest generation of molecules. These compounds will be synthesized and tested in our cell viability assays and potentially in the preclinical animal model.

Aim 1.2. Synthesis of Degraders for PIKFYVE.
We have designed proteolysis targeting chimeras (PROTACs) based on our PIKFYVE-specific inhibitors. We utilized our 181-27 or 181-24 ligand for kinase binding and thalidomide ligand (E3 ligase binding), which is capable of recruiting Cereblon (CRBN) and von-Hippel-Lindau (VHL) Cullin RING binding moieties. These PROTACs will also be synthesized in parallel and tested in our cell-culture models for their ability to specifically degrade PIKFYVE. Their effects on cell viability will also be assessed and compared to the original inhibitors.

Aim 2.1. Evaluation of anti-cancer activity and cytotoxicity to non-cancer cells.
We have started applying low-dosage chemotherapy agents (e.g., CHOP) and metabolic inhibitors to NHL cells to produce the refractory NHL cell lines. We will then apply cell viability and death assays to these cell lines (along with TNBC and DIPG cell lines) for our new compounds. By incubating PIP5K2C substrate PI5P with whole cell extracts, we showed that ATP consumption was upregulated, indicating that endogenous PIP5K2C may phosphorylate exogenously added substrate. With this assay, we further observed that compound 128-10 significantly reduced ATP consumption, implicating that 128-10 not only binds but also inhibits the kinase function of PIP5K2C. We are still in the process of establishing a kinase assay for assessing PIKFYVE activity.

Aim 2.2. Mode of action.
In this aim, we focus on dissecting the biological consequences of our PIKFYVE and PIP5K2C inhibitors to understand their mode of action. To monitor the effect of the compounds on AKT-mTOR signaling, we performed immunofluorescence staining and immunoblotting assays to monitor mTOR and AKT phosphorylation and activation. We found that inhibiting PIKFYVE may impede AKT-mTOR signaling in DIPG cells, however, the effect was much weaker in an NHL cell line. In stark contrast, AKT-mTOR signaling was activated by compound treatment in a non-viral endothelial cell line. These results lead to our hypothesis that cancer and non-cancer cells

may respond differently to our compounds. Further investigation will be carried out to test this hypothesis.

A recent report showed that inhibiting PIKFYVE impedes lysosomal function, resulting in the failure of fatty acid intake and a heavier reliance on de novo fatty acid synthesis. Based on this observation, we employ fatty acid synthesis enzyme inhibitors together with our compounds for NHL cell lines. Indeed, we discovered a synergistic response between the two molecules, which will be further tested on breast cancer and DIPG cells. This experiment may uncover novel drug combinations to fight against these refractory cancers.

Project Title: Utilizing navigation and education to improve NCCN guideline-driven care quality for patients with gastric and gastroesophageal (GEJ) junction malignancy in regions of Florida.
Principal Investigator: Steven Hochwald
Institution: Mount Sinai Medical Center
Funding: $1,467,160.00
Cancer types: Stomach, Throat

Progress Report

We have successfully launched our project in accordance with the established timelines.

This is a consortium study between Mount Sinai Medical Center (Miami Beach) and the University of Florida (Gainesville). IRB approval for the study has been obtained at both Mount Sinai Medical Center and the University of Florida. Data collection forms and an excel database has been built. We have hired a clinical research coordinator, a nurse navigator and a community outreach coordinator for Mount Sinai Medical Center. Interviews are ongoing for personnel to fill similar positions at the University of Florida.

The infrastructure is being built that will support the successful execution of the study's subsequent phases. We have purchased a website: Floridastomachcancer.com. Multiple webpages to populate this website have been developed. We expect this website to go live in the next 1-2 weeks. To promote the study, marketing materials are being developed which includes advertisements on Facebook, Instagram, and Linkedin as well as a pay for click program on Google. The goal is to raise community awareness so that patient recruitment will accelerate.

One of the Principal investigators (Dr. Nassour) has recently attended the Florida Gastroenterologic Society (September 12-14) to raise awareness about our research study with physicians in Florida. The principal investigators will soon be attending the Florida Society of Clinical Oncology (October 24-26, Orlando) to further discuss and promote this study with physicians who care for the majority of patients with gastric cancer in the state of Florida.

We are optimistic that with continued strategic management of resources, the project will achieve its planned milestones and generate meaningful impactful outcomes that contribute significantly to the field.

Project Title: Minimizing motion in SPECT-CT images of liver patients
Principal Investigator: Kenneth Chu
Institution: Mount Sinai Medical Center
Funding: $130,000.00
Cancer type: Liver

Progress Report

Proposed Hardware:
There is Hardware from Varian/Siemens that's designed to monitor respiratory gating on their CT scanners. It is called RGSC(Respiratory Gating for Scanners). A recent quote for this hardware is $89,000. What it includes is a wall mounted infrared camera which monitors a reflective marker block placed on patients xyphoid. The vertical motion is recorded, and the signal is sent to the Siemens CT scanner which allows the CT to collect images to create a 4-D CT image data set for the patient. This is proven technology, as the department of radiation oncology currently uses an older version of this device to monitor the motion of tumors within the abdomen or lung. This competes with another camera system called Identify from the same vendor, which we wrote in the grant. I am proposing that we get the RGSC system instead of Identify because the vendor said the Identify cannot provide a signal to the CT scanner but only to linear accelerators. I did not know this at the time of writing the grant.

Current Status:
Currently we have analyzed data sets from a dozen previous patients and images. And about to another dozen for my baseline as proposed in the research grant. Since June 10, we've only had two or three Y-90 liver cases where I've analyzed their SPECT- CT.

Summary:
Continue to analyze spec CT images of Y 90 patients acquired prior to June 10th.
Purchase the RGSC system from Siemens.
Continue to analyze spec CT of Y-90 patients post installation of the RGSC system period.

Project Title: MBLAC1: A Novel Target for the Treatment of Glioblastoma
Principal Investigator: Anna Knapinska
Institution: Florida Atlantic University
Funding: $561,276.00
Cancer type: Brain

Progress Report

We have made substantial progress on our project titled MBLAC1: A Novel Target for the Treatment of Glioblastoma.

Specific Aim 1: Determine whether glial MBLAC1 supports glioblastoma invasion or whether glioblastoma MBLAC1 itself enhances invasion.
We recently demonstrated differential expression of MBLAC1 in glioblastoma cells. To investigate its functional role, we proposed organoid co-cultures of glioblastoma cells and glial cells (the primary producers of MBLAC1) derived from wild-type and Mblac1 knockout (KO) mice, comparing their invasion potential to glioblastoma spheroids. Given the technical challenges of working with primary glial cells, we developed a surrogate system using HEK cells engineered to overexpress human MBLAC1. We cloned the full-length human MBLAC1 cDNA—isolated from MCF-7 cell RNA—into a GFP-tagged expression vector. Stable HEK cell lines expressing GFP-MBLAC1 were generated and validated by Western blotting. We then optimized conditions for glioblastoma spheroid co-culture with HEK/GFP-MBLAC1 cells, including seeding density, imaging parameters, and matrix composition. We replaced the initially proposed collagen I matrix with Vitrogel 3D for improved handling and tunable stiffness. Vitrogel stiffness was optimized to support glioblastoma cell invasion. Co-culture of glioblastoma cells with HEK/GFP-MBLAC1 resulted in significantly enhanced invasion compared to controls (glioblastoma alone or with HEK/GFP). After optimizing imaging and quantification methods, we tested the effect of the MBLAC1 inhibitor Ceftriaxone (50 µM) over 72 hours.

Among the glioblastoma lines tested, three showed a notable reduction in invasion and cell spreading in response to treatment.

Specific Aim 2: Development of a cell-based high-throughput screen for discovery of small molecule inhibitors targeting MBLAC1
To support high-throughput assay development, we optimized a luminescence-based readout using the CCL-1 substrate to measure intracellular Cu(I) levels, a downstream indicator of MBLAC1 activity. To detect differences in Cu(II) to Cu(I) conversion, HEK/GFP-MBLAC1 overexpressing cells were compared to HEK/GFP cells over multiple seeding densities. Efforts are currently underway to test the optimized conditions in the spheroids co-cultures and to miniaturize the assay from 96-well to 384-well format to facilitate large-scale screening.

Technical Challenges and Solutions
A significant challenge has been the poor specificity of commercially available MBLAC1 antibodies, which produce multiple non-specific bands on Western blots. The lack of a reliable human MBLAC1-positive control further hindered antibody validation. To address this, we cloned and expressed recombinant human MBLAC1 protein, which now serves as a positive control for Western blot analysis. We intend to subcontract the production of a custom anti-MBLAC1 antibody using this recombinant protein to improve detection specificity.

Summary
We have successfully established model systems to study MBLAC1's role in glioblastoma

invasion and have taken key steps toward developing a high-throughput screening platform for MBLAC1-targeting compounds. These advancements lay a strong foundation for completing the proposed aims and further therapeutic exploration.

Project Title: Discovery of marine natural product antagonists of Ewing Sarcoma target as novel therapies
Principal Investigator: Kirstie Francis
Institution: Mote Marine Laboratory
Funding: $230,578.00
Cancer type: Bone

Progress Report

Ewing Sarcoma is a rare pediatric cancer of the bones and soft tissue with more than 200 children and adolescents diagnosed each year. While early detection and diagnosis allows for improved survival, metastasis may occur in 20-25% patients, which reduces the 5-year survival rate to less than 40%. Ewing Sarcoma is caused by a genetic mutation which results in the expression of an oncogenic fusion protein. In 85-90% of patients, mutations are the result of the EWS gene on chromosome 22 binding to the FLI1 gene on chromosome 11 to form the fusion protein EWS-FLI1. This protein turns on a multitude of oncogenes which drive tumorigenesis. This protein is widely attributed to cause the initiation of Ewing Sarcoma, but there are no FDA-approved therapeutics which target the EWS-FLI1 protein directly. In this study, we aim to discover marine natural products which bind to EWS-FLI1 messenger RNA with the goal of preventing the production of the protein all together and serving as potential therapeutic(s) for the treatment of Ewing Sarcoma.

The term “natural products” refers to secondary metabolites, or genetically encoded small molecules, which are produced by organisms and are not critical for their survival but confer an evolutionary advantage for the host organism. Over 53% of all small-molecule medicines have natural product origins. Mote Marine Laboratory has a growing library of natural product extracts from a diverse collection of marine microorganisms. We intend to identify binders of EWS-FLI1 by employing a biophysical binding assay called Differential Scanning Fluorimetry (DSF) which uses fluorescent reporters to indicate whether the junction region sequence of EWS-FLI1 messenger RNA is bound by a small molecule marine natural product. In the first quarter of this project, our primary goal is to optimize the assay as defined in our Aim 1. In short, methods will be based on those previously published by the National Cancer Institute for identifying small molecule binders of target RNA and optimized to fit our conditions. The sequence from the junction region of EWS-FLI1 mRNA was purchased from a commercial vendor. Reaction conditions, microbial extract doses, RNA stabilizing and destabilizing controls, “hit” thresholds, and analysis procedures will be validated.

After optimization, we will screen a library of 500 extracts of marine microorganisms to look for EWS-FLI1 binders. The active compound(s) in the extracts will be purified using high performance liquid chromatography (HPLC) and the structure of the compound(s) will be determined using tools like mass spectrometry and nuclear magnetic resonance spectroscopy (NMR). Pure compound(s) will then be evaluated in a Ewing Sarcoma cell line to determine if they can kill the tumor cells and what impacts they may have on cancer cell signaling and EWS-FLI1 protein levels to better understand their mechanism of action. This research has the potential to identify novel drug leads for the treatment of Ewing Sarcoma.

Project Title: Improving Cancer Survival by Targeting Cancer Associated Bacteria with Novel Therapies.
Principal Investigator: Pramvir Verma
Institution: University of South Florida
Funding: $1,984,130.00
Cancer type: Lung, Breast, Colon, Prostate

Progress Report

We would like to highlight the company's ongoing efforts to advance the project objectives efficiently and compliantly. Specifically, the company is actively in the process of:

1. Engaging with the University of South Florida (USF) to leverage their expertise and facilities: This collaboration is aimed at enhancing the project's technical capabilities and accelerating key milestones. Initial discussions have focused on accessing USF's specialized research labs, faculty consultations in relevant fields of molecular biology, biochemistry and animal work. By partnering with USF, the company seeks to optimize resource utilization, incorporate cutting-edge methodologies, and ensure alignment with academic best practices, which will ultimately contribute to more robust outcomes and potential for scalable innovations.
2. Preparing the necessary documentation to obtain the required authorization from the Florida Department of Health (DOH): After an initial meeting with DOH, the team is currently reviewing regulatory guidelines to ensure all submissions meet FDOH's criteria for subcontract with USF. Once authorized, this will enable the project to proceed.

These activities demonstrate steady progress toward grant deliverables, with an emphasis on strategic partnerships and regulatory adherence. The company anticipates completing these preparatory stages within the next week, pending any unforeseen requirements.

Project Title: Transforming Cancer Care in Florida: Integrative Cancer Survivorship – Synergizing Biomarkers, Clinical Trials, and Education to Prevent Recurrence and Second Cancers
Principal Investigator: Ashwin Mehta
Institution: Memorial Healthcare System
Funding: $1,124,864.00
Cancer Type: Other (Special) – Lung, Breast, Colon, Prostate, Skin, Other solid tumors

Progress Report

This innovative research initiative explores the integration of circulating tumor DNA (ctDNA) monitoring with positive health behavior interventions to improve quality of life and outcomes for cancer survivors. By combining advanced molecular surveillance with evidence-based secondary prevention strategies, our project addresses a critical gap in survivorship care: the opportunity to detect recurrence earlier while simultaneously empowering patients through modifiable lifestyle factors that may reduce their risk of disease progression. Cancer survivors face ongoing uncertainty about recurrence, often accompanied by anxiety and diminished quality of life. Circulating tumor DNA offers a minimally invasive method to detect molecular evidence of disease recurrence months before clinical or radiographic manifestations.

When paired with targeted interventions focusing on positive health behaviors—including nutrition optimization, physical activity, stress management, and adherence to surveillance protocols—this approach has the potential to transform survivorship care from reactive to proactive. Our research team has made substantial progress across multiple implementation phases. We have successfully finalized the study protocol, which delineates our comprehensive approach to ctDNA monitoring schedules, health behavior intervention components, and quality of life assessment measures.

The protocol incorporates validated instruments for measuring patient-reported outcomes and establishes clear procedures for clinical follow-up when molecular recurrence is detected. Following rigorous review and revision, we obtained Institutional Review Board (IRB) approval for this study. The approval process required detailed attention to informed consent procedures, patient privacy protections, and the ethical considerations surrounding early detection of molecular recurrence. We developed comprehensive consent documents that clearly communicate the benefits and limitations of ctDNA testing, the experimental nature of health behavior interventions for secondary prevention, and the psychological implications of molecular monitoring results.

Significant effort has been dedicated to addressing the complex logistics of study implementation. Our team has coordinated with laboratory services to establish standardized blood collection and processing protocols for ctDNA analysis. We have developed data management systems to track longitudinal ctDNA results, intervention adherence, and clinical outcomes. Additionally, we have created patient education materials explaining ctDNA technology and health behavior modification strategies in accessible language. Recruitment strategies have been refined to ensure diverse representation across cancer types, stages, and demographic characteristics.

Most recently, as a hard start to the research project, we convened a comprehensive study initiation meeting with key personnel at our cancer center. This critical gathering brought together oncologists, research coordinators, laboratory directors, patient navigators, and behavioral health specialists. The meeting facilitated alignment on study procedures, clarified

roles and responsibilities, addressed potential implementation challenges, and fostered the multidisciplinary collaboration essential for success. Clinicians expressed enthusiasm about the potential to provide survivors with actionable information and evidence-based tools for risk reduction. Moving forward, we are implementing our patient enrollment plan and will begin data collection.

This research has the potential to establish a new paradigm in cancer survivorship care, demonstrating how molecular monitoring combined with positive health interventions can enhance both early detection and patient empowerment. The findings will inform clinical practice guidelines and policy decisions regarding survivorship care delivery in Florida and beyond.

Project Title: Cardio-Oncology Consortium to evaluate and improve the cardiovascular care of cancer patients in Florida utilizing the Global Cardio-Oncology Registry (G-COR) platform.
Principal Investigator: Diego Sadler
Institution: Cleveland Clinic Florida
Funding: $625,822.00
Cancer type: Breast

Progress Report

Since initiation, the study team has made meaningful progress toward the objectives outlined in the grant application, including enhancing recruitment feasibility, strengthening patient engagement and building infrastructure to support cachexia research in pancreatic cancer. The study officially opened to accrual on September 23, 2025, with active recruitment expected to begin the week of October 6, 2025. To improve feasibility and better align with real-world clinical workflows, we implemented a protocol amendment prior to study launch. Key eligibility criteria were revised to permit enrollment based on presumptive diagnosis of pancreatic ductal adenocarcinoma (PDAC), broaden systemic therapy requirements to include patients with developing treatment plans, and generalize staging language to reflect evolving clinical terminology. These refinements were designed to increase inclusivity, minimize missed opportunities due to diagnostic delays, and maintain scientific rigor.

Operational processes were refined to support both recruitment and participant engagement. The consent process was updated with a tiered approach, beginning with baseline assessments, and then incorporating longitudinal components once rapport is established. Remote consenting was approved, offering greater flexibility for patients and enabling advance screening to better coordinator study assessments with clinic appointments. To reduce scheduling barriers, radiological assessment was introduced as an alternative to DEXA imaging. Study infrastructure has been enhanced through the purchase and integration of Fitbits, finalization and validation of the REDCap database to support seamless data collection and monitoring, and the development of dashboards for tracking, data quality assurance, and patient compensation – ensuring participant contributions are appropriately recognized throughout the study.

In parallel, the study team has successfully onboarded the necessary research personnel and finalized training on study procedures, patient engagement strategies, and data management systems, ensuring the team is well-equipped to support the participant enrollment and day-today study operations. Beyond operational progress, the team has also prioritized dissemination and engagement with the broader research community. Abstracts describing the study's purpose, design, and innovative approach to addressing cancer-associated cachexia in pancreatic cancer have been submitted to multiple symposiums and conferences. These submissions strengthen visibility, foster collaboration, and support the study's long-term mission.

Looking ahead, our immediate focus includes launching active recruitment in early October 2025, monitoring patient engagement, protocol adherence, and maintaining high standard for data quality. These efforts will ensure the study progresses smoothly and remain aligned with overarching goal of improving early detection and management strategies for cancer cachexia in Florida. The study team remains committed to the successful execution of this research and to generating evidence that will support future interventions and advance the mission of the Florida Department of Health.

Project Title: The Live Like Bella® Comprehensive Childhood Cancer Network
Principal Investigator: Nicole de Lara Puente
Institution: Live Like Bella Childhood Cancer Foundation
Funding: $2,000,000.00
Cancer type: Brain (Glioblastoma)

Progress Report

Comprehensive Children's Cancer Network (CCCN) – First 90 Days Update
In its first three months, the Live Like Bella Comprehensive Children's Cancer Network (CCCN) has made significant strides in laying the foundation for a transformative, family-centered approach to childhood cancer care and research in Florida.

Building the Framework
To strengthen leadership, CCCN has appointed a full-time Director of Research Partnerships and engaged an experienced former health system and hospital executive to serve as chair. Both are PhD-trained and together provide significant experience in both pediatric cancer and innovative, patient-focused, interdisciplinary program development. An advisory board has also been established, bringing together experts in healthcare, technology, public policy, and project management to provide strategic guidance and oversight.

Listening to Families
Phase 1 of CCCN centers on gathering information and building relationships with key stakeholders—including researchers, clinicians, and families. A comprehensive survey was distributed to more than 2,000 caregivers of children with cancer who have received support from Live Like Bella through August 2025. With over 150 responses from families nationwide, the survey highlighted important challenges: difficulty accessing accurate information about diagnoses, limited awareness of clinical trials, and gaps in financial and psychosocial support. Analysis of these results is underway to guide future programming.

Designing a Family Resource Portal
To address these barriers, CCCN has begun development of a web-based portal. This platform will serve as a central hub for families, physicians, and researchers, offering:

- A customizable dashboard tailored to each user group
- Curated information on clinical trials sourced from clinicaltrials.gov
- Weekly news and research updates
- Community chat pages for connection and collaboration
- Biographies of Florida-based clinicians and researchers
- Dedicated family resources and general education material.

Artificial intelligence will play a key role in simplifying navigation and ensuring personalized access to information. The first portal template has been reviewed by the advisory board, with refinement underway.

Advancing Collaboration Through the Symposium
On September 12, Live Like Bella hosted its 5th Annual Pediatric Cancer Research Symposium, which drew more than 250 registrants from across the country—the most to date. What sets this event apart is the inclusion of families alongside researchers and clinicians in critical conversations. This year's program featured 29 panelists, including physicians, nurses, scientists, and mothers of survivors, discussing topics such as immunotherapy, survivorship,

neuro-oncology, and new treatment approaches. Plans are underway to host quarterly, topic-specific regional meetings to foster continued collaboration.

Looking Ahead

The first 90 days have been focused on listening, learning, and building. With strong leadership, active family engagement, and a commitment to collaboration, CCCN is poised to transform how Florida supports children with cancer and their families—providing not only cutting-edge care and research, but also the wrap-around support every family deserves.

Project Title: Leveraging Florida's Outdoor Spaces for Cancer Prevention: A Holistic Physical Activity Initiative for Cancer Survivors
Principal Investigator: Danielle Jake-Schoffman
Institution: University of Florida
Funding: $480,067.00
Cancer types: All

Progress Report

The team has been meeting weekly since the project began, and our accomplishments to date include the following:

Team Formation. We have completed three crucial hires: one full-time research scientist, Dr. Lincoln Lu, who is managing the day-to-day operations of the project and ensuring its timeline is carried out. We have also hired Mr. Wesly Menard, a PhD student in human-centered computing at the University of Florida, to co-lead the human-computer interaction side of this project under the supervision of MPI Dr. Boyer. Finally, our team is rounded out by a professional software engineer, Mr. John Terracina, an expert in app development. We have augmented this team with four outstanding undergraduate software developers, Diksha Gupta, Joelie Campana, Tyler Audino, and Shlok Nangia.

Study Protocol Development/Refinement. MPI Dr. Jake-Schoffman, who is an expert in health behavior change, and Co-I Dr. Demetra Christou, an expert in mechanistic research on exercise for disease prevention, have led the significant effort to refine our research protocols to ensure we have comprehensive inclusion/exclusion criteria and a robust plan for cycling training that accounts for the unique physical challenges that some cancer survivors may face.

Novel App Development. A significant amount of work has been completed on the Chainlink web platform, which is designed to help people plan and organize outdoor bicycle rides. Mr. Terracina and the four undergraduate software developers have collaboratively expanded the functionality of the Chainlink App to allow a smoother user experience and a find-friends functionality to make it easier for our participants to find each other in the platform and plan rides together.

Research Goal Formation. Our research team has been refining our research goals to help support the development of a sustainable mentor model that will introduce cancer survivors in Florida to outdoor cycling, leverage existing cycling networks in Florida, and aim to support the novice riders as they become cyclists who can take advantage of the accessible outdoor spaces available in Florida for recreation.
Public-Facing Materials. We have designed our public-facing website to educate the public about the study and aid in recruitment. We have also designed and iteratively refined our logo to reflect the public-facing name of our project, Pedal Florida.

Public-Private Partnerships. Finally, we have established a relationship with an established US-based bicycle company to provide affordable and high quality bicycles for our participants. We have also partnered with a local bicycle shop for transportation, initial bike setup, and maintenance.

Project Title: Bringing Cancer Research to Rural Floridians
Principal Investigator: Bradley Monk
Institution: Florida Cancer Specialists and Research Institute
Funding: $1,360,115.00
Cancer types: Lung, Breast, Colon, Prostate, Skin

Progress Report

The Bringing Clinical Trials to Rural Floridians initiative is well underway, with meaningful progress achieved towards building greater access to cancer research in rural Florida communities. Our work to date reflects strong collaboration among research staff, physicians, and new team members dedicated to patient support.

Research Navigator Program:
A cornerstone of this project is the creation of the Research Navigator role, designed to guide patients through the often-complex world of clinical trials. To ensure success, we developed a comprehensive training and onboarding plan that equips Navigators with the tools and knowledge needed to effectively support patients. Recruitment of Navigators is progressing steadily – four Navigators have already joined the team, with six additional positions expected to be filled by the end of 2025.

Clinic Integration:
Collaboration with physicians and clinic managers at participating clinics has been a critical focus. We have engaged local providers to align on workflows and ensure seamless integration of Navigators into clinical settings. These partnerships are laying the groundwork for improved patient awareness and improve trial enrollment experiences.

Educational Tools and Outreach:
Patient education is essential to this initiative. We are currently developing marketing and educational materials to improve clinical trial awareness and highlight the potential benefits of trials. At the same time, we are advancing plans for focus groups that will allow us to gather valuable feedback directly from patients and community members. These sessions will inform how we tailor resources to meet unique needs of rural populations. These focus groups are expected to begin before the end of 2025 and IRB approval was obtained August 2025. A key milestone in progress is the redesign of our program website ClinicalTrialsNavigator.com. Updates are being made to ensure patient can not only learn more about clinical trials, but also interact directly with Research Navigators through user-friendly, interactive chat options. This web-based approach will extend Research Navigator reach beyond clinical walls making guidance and support accessible to more rural individuals.

Community Connections:
Recognizing the importance of community input, we are also designing outreach strategies to connect Research Navigators with local patient advocacy groups. These partnerships come at physician recommendation and support connections to clinical trials. These partnerships will strengthen clinical trial awareness efforts, amplify patient engagement efforts, and create an extended network across rural Florida communities.

Next Steps:
Over the next several months our efforts will expand to active patient engagement. This includes completing our planned focus groups, beginning continuous community engagement, and hosting our first Town Hall events.

Project Title: Advancing Precision Medicine for Pediatric Oncology with Whole Genome Sequencing (WGS) and Clinical Trials Matching
Principal Investigator: David Seo
Institution: Nicklaus Children's Health System
Funding: $1,957,615.00
Cancer type: Other (Special) – Pediatric Oncology

Progress Report

During this reporting period, our team made progress on several key components of the project.

First, we are working together with the team from the University of Miami (UM) on the technical foundation to install a new, separate version of the Sylvester Data Portal (SDP) into the Nicklaus Children's Health System (NCHS) technology infrastructure. We have started setting up the Azure cloud component at NCHS into which the new SDP will be installed. This includes the technical part of setting up the Azure cloud instance as well as putting into place the IT security measures to safely install and monitor SDP inside of the NCHS network.

Second, we completed all of the Institutional Review Board (IRB) approvals for the project. This was an important milestone on our critical path and allows all of the research activities to move forward.

Third, we are building the database that will hold all existing tumor genomic profiles already performed for clinical reasons at NCHS. At the same time, we are working on the data use agreements with the outside genomic testing vendors for them to return patient genomic testing data back to NCHS. We will incorporate this information into the database we are creating.

Fourth, we are started cataloging our existing tumor tissues in storage for different tissue types. We are also putting together the equipment and workflows to start storing fresh tumor samples. This work is in preparation for sending the samples for whole genome sequencing.

Fifth, we are working on the AI-powered clinical trials matching system. We have connected to the clinicaltrials.gov website API connection to start ingesting the clinical trials data into our system. We can then start to work on the specialized database system (vector and graph databases) to create the matching tool.

Finally, we are in the process of making a key hire which is the data scientist that will accelerate the technical and analytic portions of the project.

In summary, our work this quarter focused on setting up the technical components, completing the regulatory requirements, building the databases and preparing tumor samples for sequencing. We have made appropriate progress to keep us on track to complete the project and set us up for the next quarter's work.

Appendix 4. Best Practice Recommendations

1. **Project Title: Florida Partnership for Adding Social Context to Address Cancer Survivorship Outcomes (ASCENT)**
   Principal Investigator: Dejana Braithwaite
   Institution: University of Florida
   Funding: $598,993.00
   Cancer types: Colon, Gynecologic

   Best Practice Recommendations:

   While data collection has not yet begun, this project is designed to inform best practices for health care providers and support the development of digital tools that connect cancer patients with resources. The overarching goal is to improve food security and diet quality among the cancer population. We anticipate further recommendations will emerge as data collection begins and we gain insights into patient and provider experiences.

2. **Project Title: Exosome Interception: A New Strategy to Stop Breast Cancer Metastasis**
   Principal Investigator: Annette Khaled
   Institution: University of Central Florida
   Funding: $257,948.00
   Cancer type: Breast

   Best Practice Recommendations:

   Future best practices from our research may include a new adjuvant strategy to prevent breast cancer recurrence and spread by blocking cancer-promoting exosomes. This approach could reduce the need for chemotherapy or hormone therapy, helping to minimize their side effects.

3. **Project Title: Make FDA-Approved Anticancer Drugs Effective for the Most Difficult-to-Treat Breast Cancer Patients by Targeting a Novel Drug-Resistant Cancer Gene Using Innovative Drug-Delivery Technologies**
   Principal Investigator: Jihe Zhao
   Institution: University of Central Florida
   Funding: $510,656.00
   Cancer type: Breast

   Best Practice Recommendations:

   If the proposed experiments go as expected in the end of the grant term, it will suggest that cancer cell and cancer gene selectively targeted combination of currently available chemo and immune anticancer therapy may be a new option for effectively treating patients with the most difficult to treat, drug resistant triple negative breast cancer.

4. **Project Title: A Multimodal Lung Cancer Risk Assessment Model using Comprehensive Data Integration**
   Principal Investigator: Nezamoddin Kachouie
   Institution: Florida Institute of Technology
   Funding: $422,453.00
   Cancer type: Lung

   Best Practice Recommendations:

   Upon completion, the multimodal lung cancer risk assessment model will offer health care providers a more comprehensive and individualized view of each patient's risk by integrating clinical, genetic, imaging, and behavioral factors. This richer perspective will enable clinicians to make more informed and personalized treatment decisions, selecting care pathways that best match the unique needs of each patient. In doing so, the model has the potential to guide the adoption of best practices in oncology care, fostering more effective, patient-centered treatments and improving overall outcomes.

5. **Project Title: Advancing Personalized Ion Radiation Therapy: Integrating Cellular Pathomics and Relative Biological Effectiveness Modeling for Improved Cancer Outcomes in Florida.**
   Principal Investigator: Chris Beltran
   Institution: Mayo Clinic
   Funding: $946,965.00
   Cancer type: Pancreatic, Brain

   Best Practice Recommendations:

   This work is still preliminary, but for health care providers that treat cancer with ion-radiation, this will establish the preferred method for characterizing tumor and normal tissue for relative biological calculations.

6. **Project Title: A Twin SQL and Smart Cancer Repository and Query System with Analytical Intelligence Capability and Shared Access**
   Principal Investigator: Nezamoddin Kachouie
   Institution: Florida Institute of Technology
   Funding: $600,071.00
   Cancer type: Lung

   Best Practice Recommendations:

   Upon completion, the repository will provide a powerful infrastructure that enables health care providers to share knowledge, exchange clinical experiences, and collaboratively identify strategies that improve patient outcomes. By integrating diverse insights and evidence, the system has the potential to highlight and recommend best practices that can be adopted in real-world care, leading to more effective, consistent, and patient-centered cancer treatment.

7. **Project Title: Cancer CARE Beyond Walls– A Pilot Clinical Trial to Evaluate Administration of Cancer Directed Therapy in the Home Versus in Clinic for Patients Residing in the Florida Panhandle and Surrounding Area**
   Principal Investigator: Roxana Dronca
   Institution: Mayo Clinic
   Funding: $1,867,284.00
   Cancer types: Lung, Breast, Colon, Prostate, Skin

   Best Practice Recommendations:

   Based on early implementation efforts, several best practices have emerged that will help guide future expansion. First, offering flexible care delivery options, either at home or via a mobile unit, is essential for meeting the needs of patients living in geographically remote areas, including those not serviced by existing home health agencies. Second, success hinges on infrastructure readiness, including seamless coordination among the command center team, home health partners, and medication delivery logistics. Third, early and ongoing patient engagement is vital, particularly when it comes to addressing digital literacy gaps and building trust in non-traditional care settings. As this program continues to grow, it positions Florida as a national leader in transforming how care is delivered to rural populations, with a steadfast commitment to ensuring that no patient is left behind because of geography. This pilot program is expected to improve patient satisfaction, reduce financial stress, provide access to high-quality cancer care, and inform statewide and national models for expanding cancer care access in rural and underserved communities.

8. **Project Title: Comparison of Cone Beam Breast CT with digital breast Tomosynthesis and contrast-enhanced breast MRI**
   Principal Investigator: Stuart Kaplan
   Institution: Mount Sinai Medical Center
   Funding: $600,000.00
   Cancer type: Breast

   Best Practice Recommendations:

   We anticipate Breast CT to become incorporated into the overall Breast cancer screening and diagnostic process in the future.

9. **Project Title: Minimizing motion in SPECT-CT images of liver patients**
   Principal Investigator: Kenneth Chu
   Institution: Mount Sinai Medical Center
   Funding: $130,000.00
   Cancer type: Liver

   Best Practice Recommendations:

   Inform CT technicians to disable the CT scanners automatic announcement telling the patient to "take a deep breath and hold it"

10. **Project Title: AI-Driven Early Detection of Cachexia in Pancreatic Cancer and Feasibility of Diet and Exercise Interventions**
    Principal Investigator: Ghulam Rasool
    Institution: H. Lee Moffitt Cancer Center & Research Institute, Inc.
    Funding: $1,054,076.00
    Cancer type: Pancreatic

    Best Practice Recommendations:

    Although recruitment has not yet begun, early implementation efforts and protocol refinements have revealed several promising practices that may inform future recommendations for health care providers treating pancreatic cancer and cancer-associated cachexia. For example, permitting engagement based on a presumptive diagnosis, rather than waiting for full confirmation, may allow for earlier intervention and better alignment with clinical workflow.

    Similarly, broadening eligibility to include patients with treatment plans under development reflects the dynamic nature of oncology care and could support more inclusive access to supportive services. The tiered consent approach, which introduces care components gradually, may help reduce patient overwhelm and improve understanding, while remote education and consent tools offer flexibility for patients facing logistical barriers.

    Additionally, incorporating radiological imaging as an alternative to DEXA scans provides practical flexibility for body composition assessment when scheduling or equipment limitations arise. These insights, while preliminary, suggest potential strategies for improving patient-centered care and operational efficiency in clinical settings. As recruitment progresses, we will continue to evaluate and refine these approaches to determine their applicability as formal best practices.

The Florida Senate

APPEARANCE RECORD

Deliver both copies of this form to
Senate professional staff conducting the meeting

12/9/25
Meeting Date

Health Policy
Committee

DOH Cancer Initiat
Bill Number or Topic

Amendment Barcode (if applicable)

Name Dr. Emma Spencer

Phone

Address 4052 Bald Cypress Way
Street

Email John.bell@FLHealth

Tallahassee FL 32399
City State Zip

Speaking: ☐ For ☐ Against ☑ Information **OR** Waive Speaking: ☐ In Support ☐ Against

PLEASE CHECK ONE OF THE FOLLOWING:

☐ I am appearing without compensation or sponsorship.

☐ I am a registered lobbyist, representing:

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While it is a tradition to encourage public testimony, time may not permit all persons wishing to speak to be heard at this hearing. Those who do speak may be asked to limit their remarks so that as many persons as possible can be heard. If you have questions about registering to lobby please see Fla. Stat. §11.045 and Joint Rule 1. 2020-2022JointRules.pdf (flsenate.gov)

This form is part of the public record for this meeting.

S-001 (08/10/2021)

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

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Appropriations Committee on Criminal and Civil Justice
Appropriations Committee on Pre-K - 12 Education
Banking and Insurance
Education Pre-K - 12
Health Policy
Judiciary
Rules

JOINT COMMITTEE:
Joint Committee on Public Counsel Oversight

SENATOR ROSALIND OSGOOD
32nd District

December 3rd, 2025

Dear Chair Burton,

I hope you are doing well. I am writing to formally request that I be excused from the Health Policy Committee meeting scheduled for Tuesday, December 9th, 2025, due to an unmovable commitment. While I regret missing the discussions and any important matters on the agenda, this prior commitment requires my attention.

Thank you for your time and consideration.

Sincerely,

Rosalind Osgood

Senator Rosalind Osgood

REPLY TO:
❒ 8491 West Commercial Boulevard, Tamarac, Florida 33351 (954) 321-2705
❒ 213 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5032

Senate's Website: *www.flsenate.gov*

BEN ALBRITTON
President of the Senate

JASON BRODEUR
President Pro Tempore

THE FLORIDA SENATE

Tallahassee, Florida 32399-1100

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Joint Legislative Auditing Committee

SENATOR TRACIE DAVIS
Democratic Leader Pro Tempore
5th District

December 3, 2025

The Honorable Colleen Burton
Health Policy, Chair
111 W. Madison Street
Tallahassee, FL 32399-1100

Dear Chair Burton,

I respectfully request an excused absence from the December 9, 2025, Health Policy Committee meeting.

Thank you for your consideration.

Sincerely,

Tracie Davis
State Senator
District 05

❒ 2933 North Myrtle Avenue, Suite 201, Jacksonville, Florida 32209 (904) 359-2575
❒ 210 Senate Building, 404 South Monroe Street, Tallahassee, Florida 32399-1100 (850) 487-5005

CourtSmart Tag Report

Room: KB 412 **Case No.:** **Type:**
Caption: Senate Committee on Health Policy **Judge:**

Started: 12/9/2025 10:11:42 AM
Ends: 12/9/2025 11:20:43 AM **Length: 01:09:02**

10:11:46 AM Call to Order
10:12:00 AM Roll Call
10:12:03 AM Quorum present
10:12:38 AM Opening Remarks-Vice Chair Harrell
10:13:21 AM Tab 2
10:14:12 AM Presentation on the Cancer Connect Collabrative's Annual Report, Department of Health
10:14:56 AM Dr. Emma Spencer, DOH
10:28:53 AM Senator Trumbull
10:29:52 AM Dr. Spencer
10:31:05 AM Senator Trumbull
10:32:35 AM Dr. Spencer
10:34:03 AM Senator Harrell
10:34:28 AM Dr. Spencer
10:35:27 AM Senator Harrell
10:36:01 AM Dr. Spencer
10:37:42 AM Senator Harrell
10:37:51 AM Dr. Spencer
10:37:55 AM Senator Harrell
10:38:21 AM Dr. Spencer
10:38:53 AM Senator Harrell
10:40:18 AM Senator Gaetz
10:40:37 AM Dr. Spencer
10:41:14 AM Senator Gaetz
10:41:55 AM Dr. Spencer
10:43:10 AM Tab 1
10:43:15 AM SB 312
10:43:22 AM Senator Rodriguez
10:45:10 AM Senator Berman
10:45:40 AM Senator Rodriguez
10:46:10 AM Senator Berman
10:46:39 AM Senator Rodriguez
10:47:03 AM Senator Berman
10:47:26 AM Senator Rodriguez
10:47:51 AM Senator Harrell
10:48:11 AM Senator Rodriguez
10:49:15 AM Public Testimony
10:49:41 AM Alexis Hall
10:53:17 AM Meredith Fischer
10:56:37 AM Lynda Bell, Florida Right to Life
11:03:44 AM Charlene Reynolds
11:07:07 AM Hattie Bryant
11:10:08 AM Bruce Camber
11:14:40 AM Leonard Hock
11:18:01 AM Waives Read into Record
11:18:44 AM Senator Rodriguez
11:19:36 AM Roll Call for SB 312
11:20:17 AM Reported Favorably
11:20:35 AM Adjourned