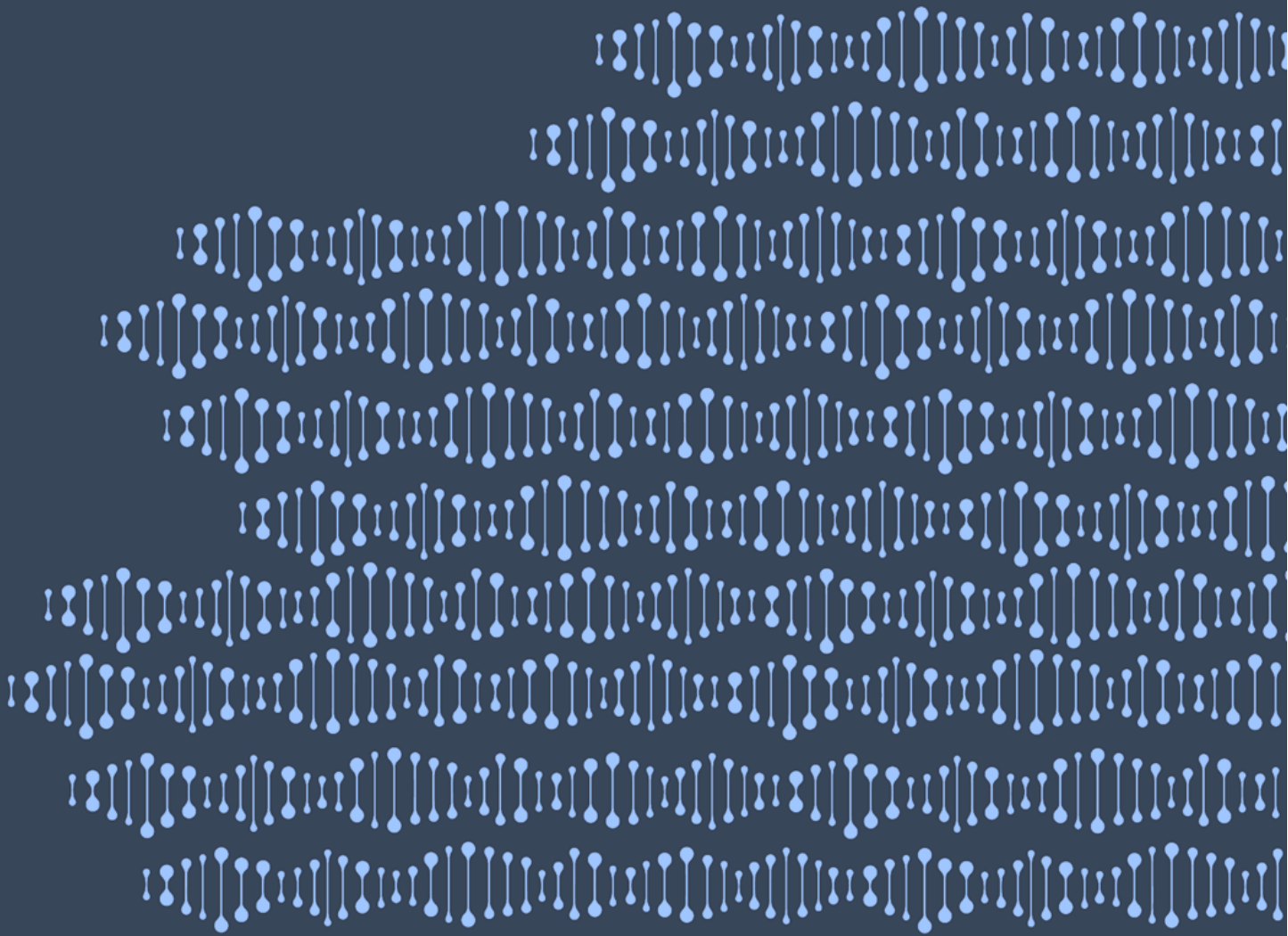
Cancer Prevention & Research Institute of Texas

Program Priorities 2017



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ABOUT CPRIT PROGRAM PRIORITIES PROJECT

CPRIT is governed by Health and Safety Code: Chapter 102. Legislation from the 83rd Texas Legislature modified that code to include enhancements to CPRIT's governance and operations. One of the specific enhancements requires CPRIT's Oversight Committee to establish program priorities on an annual basis. The priorities are intended to provide transparency in how the Oversight Committee directs the orientation of the agency's funding portfolio between and within its three programs as well as guide CPRIT staff and Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and the evaluation of applications submitted in response to those RFAs.

The Oversight Committee priorities are to be reviewed and adjusted annually as circumstances change and new information is found concerning cancer-related advances in prevention, academic research and product development research.

CPRIT Purpose

Health and Safety Code: Chapter 102

Sec. 102.002. PURPOSES. The Cancer Prevention and Research Institute of Texas is established to:

(1) create and expedite innovation in the area of cancer research and in enhancing the potential for a medical or scientific breakthrough in the prevention of cancer and cures for cancer;

(2) attract, create, or expand research capabilities of public or private institutions of higher education and other public or private entities that will promote a substantial increase in cancer research and in the creation of high-quality new jobs in this state; and

(3) develop and implement the Texas Cancer Plan.

Program Priorities Legislative Mandate

Health and Safety Code: Chapter 102

Sec. 102.107. POWERS AND DUTIES. The oversight committee shall:

(1) hire a chief executive officer;

(2) annually set priorities as prescribed by the legislature for each grant program that receives money under this chapter; and

(3) consider the priorities set under Subdivision (2) in awarding grants under this chapter.

PROCESS TO DEVELOP PROGRAM PRIORITIES

The Oversight Committee approved the 2015 program priorities in November 2014 after a six month process that included subcommittee meetings and public input. The program priorities were subsequently incorporated into the requests for applications released by each program. The Oversight Committee reaffirmed the program priorities for 2016 in November 2015. In the fall of 2016 the Oversight Committee Subcommittees worked with the Program officers and respective Advisory Committees to review and update the program priorities for 2017.

SCOPE OF PROGRAM PRIORITIES PROJECT

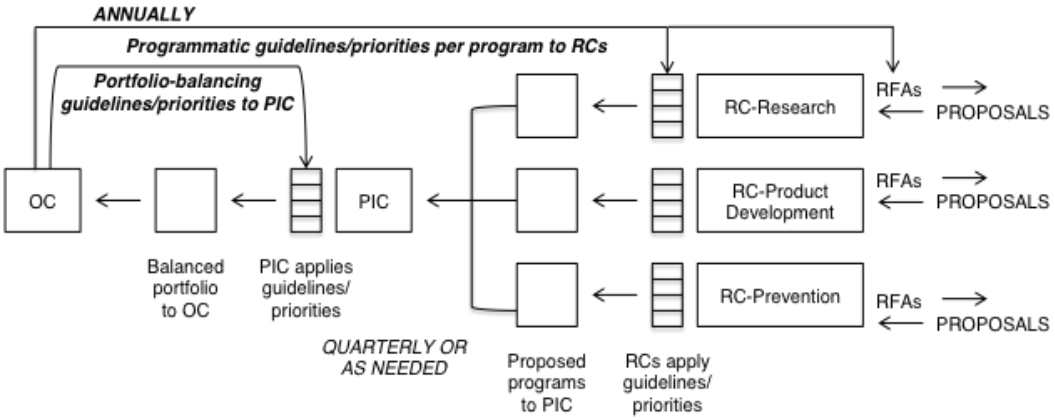
The Program Priorities Project establishes priorities at two levels of CPRIT's grant making process:

- **Priorities Within Each of CPRIT's Programs** – priorities to inform staff and respective Peer Review Councils (RCs) on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications submitted in response to those RFAs.

- **Priorities Across CPRIT's Three Programs** – priorities to inform the Program Integration Committee (PIC) on balancing the portfolio across the academic research, prevention and product development research programs.

CANCER PREVENTION & RESEARCH INSTITUTE OF TEXAS

Priorities and CPRIT's Grant Making Process



CPRIT'S LONG-TERM VISION

As the Oversight Committee set out to establish program priorities, it began by defining the long-term vision for the agency and each of the three programs in alignment with CPRIT's mandated purpose.

Innovative projects funded by CPRIT will result in:

- A decrease in the burden of cancer in Texas through preventive measures, new diagnostics and treatments, and effective translation of discoveries into products;
- A recognition of and focus on disparities in cancer incidence, mortality and access to care;
- Significant advancements in the scientific understanding of cancer; and
- An enhanced and expanded life sciences infrastructure in the state as a result of recruiting researchers, training health care/science professionals, attracting companies and supporting investigator startups.

PRIORITIES WITHIN EACH OF CPRIT'S PROGRAMS

Priorities within each of CPRIT's programs –academic research, prevention and product development research– will inform staff and respective Peer Review Councils on the development and issuance of program-specific Requests for Applications (RFAs) and evaluation of applications to those RFAs.

CPRIT's three programs are currently guided by established key principles essential to executing CPRIT's purpose. The main principle underlying all three programs is that they will continue to ensure only applications with scientific merit will move forward in CPRIT's peer review grant process. In addition, the programs have established principles that are unique to each program. The new program priorities will supplement these principles to guide the selection of meritorious applications to address CPRIT's strategic priorities as set annually by the Oversight Committee.

*It is important to note that these priorities **do not** exclude funding in areas outside of the identified priorities.*

Academic Research Program

Background: The goal of CPRIT's academic research program is to discover new information about cancer that can lead to prevention, early detection, and more effective treatments; translate new and existing discoveries into practical advances in cancer diagnosis, treatment, and survivorship; and increase the prominence and stature of Texas in the fight against cancer. CPRIT's strategy is to support the most creative ideas and the most meritorious projects brought forward by the cancer research community in Texas. The overarching principles for awarding CPRIT funds will continue to be scientific excellence and impact on reducing the burden of cancer.

In addition CPRIT's academic research program will seek to fund projects in critical, but underfunded areas of cancer research. Areas of opportunity for strategic deployment of funds include prevention and early detection research; computational biology and analytic methods; childhood cancers; and intractable cancers with particular emphasis on population disparities and cancers of significance in Texas (e.g. lung, liver, and cervical cancers).

Finally, it is critically important to add to the life sciences infrastructure in the State of Texas. This will enable CPRIT's impact on cancer research to extend for years beyond the lifetime of the program. Most important to increasing infrastructure is the recruitment of preeminent researchers and the investment in core facilities. New researchers will bring additional resources to the State,

including research funding and new expertise, as well as help build the critical mass of science needed to attract investments in the development of products for cancer prevention, diagnosis, and treatment. Investments in core facilities will assure that these and other cancer researchers in Texas have access to the most up-to-date technologies needed for cutting-edge cancer research. Also critical are the training programs that aim to produce the next generation of cancer researchers and increase the diversity of the cancer research workforce.

Established Principles:

- Scientific excellence and impact on cancer
- Targeting underfunded areas
- Increasing the life sciences infrastructure

Academic Research Program Priorities
• Recruitment of outstanding cancer researchers to Texas • Investment in core facilities • A broad range of innovative, investigator-initiated research projects • Prevention and early detection • Computational biology and analytic methods • Childhood cancers • Population disparities and cancers of importance in Texas

Prevention Program

Background: The following principles have guided the prevention program since its inception in 2009. These principles have informed the development of the requests for applications (RFAs) and the evaluation of applications submitted in response to the RFAs.

Through the prevention program, CPRIT seeks to fund projects that:

- Are evidence based – offering effective prevention interventions based on the existing body of knowledge about and evidence for cancer prevention.
- Deliver primary, secondary, or tertiary (includes survivorship) prevention interventions – providing state of the art preventive clinical services and tailored, culturally appropriate, and accurate information to the public and health professionals.

In addition, the program has focused on providing access to underserved populations and serving the populations in most need including underinsured and uninsured individuals and those disproportionately affected by cancer.

In order to achieve some degree of balance to the prevention program portfolio, the Prevention Review Council (PRC) conducts a programmatic review of applications under consideration. During programmatic review, the Prevention Review Council (PRC) evaluates applications judged to be meritorious by prevention review panels. Programmatic considerations include:

- Potential for impact
- Geographic distribution
- Cancer type
- Type of program or service

While these principles provide guidance for the program, identifying priorities based on areas where significant cancer incidence and mortality disparities exist focuses the program further on areas of greatest need and greatest potential for impact.

Data on cancer incidence, mortality and disparities (geographic, ethnic, etc.) are reviewed annually to identify priorities and identify areas of emphasis. This information informs the development of RFAs and informs programmatic decisions during the PRC level of review.

Established Principles:

- Fund evidence-based interventions and their dissemination
- Support the prevention continuum of primary, secondary and tertiary (includes survivorship) prevention interventions

Prevention Program Priorities
• Populations disproportionately affected by cancer incidence, mortality or cancer risk prevalence • Geographic areas of the state disproportionately affected by cancer incidence, mortality or cancer risk prevalence • Underserved populations

Product Development Research

Background:

The Product Development Research Program funds private companies to develop products that benefit cancer patients. Developing novel cancer treatments results from a series of research and development activities.

1. Basic research provides understanding of biological principles, the causal factors of disease, the natural history of disease progression and how disease may be cured or ameliorated. Basic research is typically is conducted in a university setting funded primarily by government grants.
2. Applied research involves inquiry involving the practical application of science. In CPRIT's context it demonstrates methods to diagnose or treat disease. It is typically conducted in a university setting using government and/or private funds. Promising technologies may be patented and licensed to private companies for continued development or spun out from the university in nascent companies for development.
3. The process of product development converts a one-time phenomenon to a safe and reliable product usable in a clinical setting.
4. Clinical research confirms the safety and efficacy on the target patient population.
5. Regulatory approval is required prior to commercial use. Product development, clinical research and regulatory approval are historically conducted by startup companies funded by private investors and, in recent years, by the public sector to promote economic development.

As a product moves through this process, risks are reduced at each step. Earlier stage programs have higher risk and are the least likely to attract private capital. CPRIT typically invests in early stage companies where private capital is hardest to obtain. CPRIT uses subject matter expert peer reviewers to identify the most promising projects. CPRIT's investment in early stage companies increases the number of cancer therapies in development in Texas thereby stimulating the Texas life sciences ecosystem.

CPRIT uses its limited resources to maximize clinical benefits including curing disease, slowing progression, earlier detection, mitigating side effects, and/or reducing cost of care.

More scientifically and commercially attractive product development opportunities exist than CPRIT can fund. Therefore, to invest strategically the Product Development Research focuses on the following:

Novel Projects

1. Novel ideas that offer therapeutic or diagnostic benefits not currently available; i.e., disruptive technologies.
2. Projects addressing large or challenging unmet medical needs.
3. Projects based on sound scientific research, with strong management and compelling business plans that will be attractive to private investment.
4. Early stage projects when private capital is most difficult to obtain.

Grow the Ecosystem

1. Catalyze the Texas life sciences ecosystem by supporting new company startups in Texas or attracting promising companies to Texas.
2. Identify companies that will recruit staff with life science industry expertise, especially experienced C-level staff to seed clusters of life science expertise at various Texas locations.
3. Support commercialization of technologies developed at Texas institutions.

Established Principles:

- Support commercial development of novel products that address unmet cancer diagnosis and treatment needs.
- Stimulate the Texas life sciences ecosystem by funding in spaces that lacks private investment (the technology "Valley of Death" subsequent to research grants but before private investment).
- Invest in projects based on sound scientific research with strong management and sound business plans that will attract future private investment.

Product Development Research Program Priorities
• Funding novel projects that offer therapeutic or diagnostic benefits not currently available; i.e., disruptive technologies • Funding projects addressing large or challenging unmet medical needs • Investing in early stage projects when private capital is least available • Stimulating commercialization of technologies developed at Texas institutions • Supporting new company formation in Texas or attracting promising companies to Texas that will recruit staff with life science expertise, especially experienced C-level staff to lead to seed clusters of life science expertise at various Texas locations • Providing appropriate return on Texas taxpayer investment

PRIORITIES ACROSS CPRIT'S THREE PROGRAMS

Establishing priorities across CPRIT's academic research, prevention and product development research programs will inform the Program Integration Committee (PIC) on balancing the portfolio across the three programs.

CPRIT's structure, which includes programs in academic research, prevention and product development research, presents a unique opportunity for funding projects that span the continuum from discovery to delivery to the public and creating synergy across the spectrum. While CPRIT programs would continue to fund a broad range of programs and cancer types, selecting areas of emphasis where CPRIT could have an impact and distinguish it from other funding sources provides a basis for focusing resources and guiding decisions when resources are limited. The recommended areas of emphasis outlined below also correspond to unmet needs – places in the cancer research and care continuum where existing institutions have not provided strong programs or results.

It is important to note that these priorities serve as strategic areas of emphasis and do not exclude funding in areas outside of the identified priorities.

Prevention and Early Detection Initiatives

Rationale: Nowhere is there greater potential to reduce the burden of cancer than by reducing its incidence. This spares people and families from the psychological and emotional trauma of a cancer diagnosis, the often devastating physical consequences of cancer therapies, and the financial burden associated with cancer treatment. In addition, the current emphasis in cancer research on finding cures for advanced cancers has serious limitations. Thus far, attempts to control cancer by chemotherapy, radiation, and even targeted therapy have been thwarted by the ability of cancer cells to develop resistance to these treatment modalities. Detecting cancer early in its development is a more desirable approach to cancer control. In spite of the potential impact of prevention and early detection on reducing the cancer burden, these areas of cancer research receive little funding relative to funding devoted to curing advanced cancer.

Emphasis: Ideally, academic research would create the evidence base for new approaches to prevention and early detection, product development research would provide new methods, diagnostics, imaging or devices for early cancer detection, and the prevention program would implement interventions to put these new approaches into practice once a solid evidence base of effectiveness exists. Strategies would include each program issuing either a targeted RFA or listing prevention or early detection as an area of emphasis (among others) within current RFAs. In addition, the programs can explore RFAs that could span programs, e.g. RFAs that would support a research component to a prevention project.

Early Translational Research

Rationale: One well-documented impediment to bringing the results of basic research to bear on cancer is the shortage of funding to translate new discoveries into practical advances for cancer patients. Research and development are needed between the

stages of discovery science, traditionally funded by grants from federal sources and foundations, and late term development and commercialization of drugs, devices, diagnostic tests, and biologicals traditionally funded by private sector industries. Data indicate that such translational research is underfunded and would benefit from additional investment. Funding such research and development by CPRIT could have the added benefit of stimulating public-private partnerships and bringing new commercial investments to Texas.

Emphasis: Funding translational research that bridges the gap between basic research and product development, and between research on preventive measures and new technologies for early detection and adaptation of tested interventions represents opportunities for inter-program strategic investment by CPRIT. The time needed to move some projects from research to products is often lengthy and may limit the role of the prevention program in this area of emphasis.

Enhance Texas' Research Capacity and Life Science Infrastructure

Rationale: CPRIT's statute emphasizes enhancing research superiority, increasing applied science and technology research capabilities and increasing high-quality jobs in the state. All three programs contribute to enhancing the research, life science and cancer control workforce and infrastructure in the state.

Emphasis: Establishing a critical mass of cancer researchers in Texas is possible by supporting the recruitment of cancer scientists and clinicians, at all career levels, to academic institutions in Texas and through training programs in which pre- and post-doctoral fellows are educated to become cancer researchers. The recruitment program has been successful in enhancing Texas' cancer research efforts and increasing the external visibility of the state in the medical and scientific communities.

CPRIT's investments in product development help to build Texas' life-science industry. While bringing a product to market can take time, jobs and economic activity are generated throughout the process. Every CPRIT award includes

intellectual property requirements that specify a revenue return to Texas through the successful development of CPRIT-funded drugs, devices, diagnostics or services.

The prevention program supports the education and training of health care professionals and community workers, thereby increasing the state's capacity for cancer prevention and control activities. By requiring collaborative partnerships, the program also creates incentives for organizations and individuals to collaborate to tackle community problems through networks that can mobilize resources and avoid duplication of efforts. Implementing system changes (such as reducing wait times between screening and diagnostics, implementing patient reminder systems) by CPRIT funded programs also improves the infrastructure for the delivery of preventive interventions.

Summary: Priorities across CPRIT's Three Programs

Below is a table illustrating how each of CPRIT's three programs could implement the recommended areas of emphasis outlined above.

	Prevention and Early Detection Initiatives	Early Translational Research	Enhance Texas' Research Capacity and Life Science Infrastructure
Academic Research Program Implementation	Create the evidence base for new approaches to prevention and early detection.	Identify CPRIT funded basic research that could translate new discoveries into practical advances.	Increase workforce and infrastructure: researcher recruitment, training grants and core facilities.
Prevention Program Implementation	Implement programs to put these new approaches into practice and continue to fund what is known to work (evidence based).	Due to long lead-time to product development, there may be limited role for prevention to implement programs resulting from this research.	Implementing systems change, developing partnerships and collaborations, training of community and healthcare providers, and creating new jobs.
Product Development Research Program Implementation	Fund new tools, technologies, methods and devices for early cancer detection and prevention.	Fund translational research that bridges the gap between basic research and product development.	Build up life sciences infrastructure and industry in Texas and create new high paying jobs.