

# Florida Department of Health Biomedical Research Advisory Council (BRAC) Grants

William G. "Bill" Bankhead Jr., and David Coley Cancer Research Program
James and Esther King Biomedical Research Program
Live Like Bella Pediatric Cancer Research Initiative

**Funding Opportunity Announcement** 

#### **Fiscal Year 2025-2026**

#### **Award Period:**

July 1, 2025 – June 30, 2026

**Letters of Intent Due:** December 16, 2025 **Applications Due:** January 12, 2026

NOTE: All awards in response to this Funding Opportunity Announcement (FOA) are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this FOA, all applicants acknowledge and consent to this and all other conditions in this FOA.

Direct all questions about this FOA, online application process, and related issues to:

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#### 1. FOA KEY POINTS

Applicants should note the following key points:

- 1. This FOA supports applications for cancer research that advance progress toward cures for cancer (Bankhead-Coley Program); biomedical research that addresses the heath care problems of Floridians in the areas of tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease (James and Esther King Program); and for pediatric cancer, research that advances the search for a cure for pediatric cancers (Live Like Bella Initiative). Refer to the Eligibility section of this FOA for more information.
- 2. Priority will be given to project proposals that focus on reduction of morbidity and mortality; improved screening and accuracy; resistance to front-line treatments in recurrent disease in certain cancers; prevention and treatment research evaluating programs for tobacco use reduction and prevention (James and Esther King Program only); research focused on the biologic mechanisms of use of electronic cigarettes, transition from combustible tobacco to electronic cigarettes, relationship between electronic cigarette use and different cancers, effects of electronic cigarette use in individuals treated for cancer, and intervention to reduce or prevent electronic cigarette use. (James and Esther King Program only); and examine the relationship between obesity and cancer, cancer treatment responsiveness, and cancer treatment-related morbidities. Refer to the Research Priorities section of this FOA for more information.
- 3. Applicants are required to submit a Work Plan with each application for the entire project timeframe. The Work Plan must include identified milestones for the project and will serve as contract deliverables for grant-funded projects. An Work Plan template will be provided in the online application and Biomedical Research Program's Grant Management Forms and Resources web page on the Florida Department of Health's website.
- 4. Applicants must identify one Corresponding Principal Investigator, herein named the Principal Investigator (PI), for each project proposal submitted. Refer to the <u>Eligibility</u> section of this FOA for more information about the PI.
- 5. Co-Principal Investigators (Co-Pls) are allowed under this FOA, though there must be only one PI listed for each grant project. Co-Pls are optional and serve as secondary Pls on the project. Refer to the <u>Eligibility</u> section of this FOA for more information about Pls and Co-Pls.
- A project proposal may be submitted <u>only once</u> for this FOA during the current grant funding period, defined as either a new or a resubmission proposal. Resubmission proposals are project proposals that were submitted in previous grant cycles but not funded.
- 7. Specific grant funding amounts are available for the grant categories outlined in the <u>Grant Categories</u> section of this FOA. Refer to the <u>Funding Information</u> section of this FOA for details on the maximum amounts available. Funding for this FOA is subject to the annual appropriation of funds by the Florida Legislature and granted spending authority to the Department.

#### 2. INTRODUCTION

The Biomedical Research Advisory Council (BRAC) was created within the Florida Department of Health (Department), under section 215.5602, Florida Statutes. BRAC advises the State Surgeon General as to the direction and scope of the biomedical research program grants. The responsibilities of the BRAC may include, but are not limited to:

- 1. Providing advice on program priorities and emphases.
- 2. Providing advice on the overall program budget.
- 3. Participating in periodic program evaluation.
- 4. Assisting in the development of guidelines to ensure fairness, neutrality, and adherence to the principles of merit and quality in the conduct of the program.
- 5. Assisting in the development of appropriate linkages to nonacademic entities, such as voluntary organizations, health care delivery institutions, industry, government agencies, and public officials.
- 6. Developing criteria and standards for the award of research grants.
- 7. Developing guidelines relating to solicitation, review, and award of research grants and fellowships, to ensure an impartial, high-quality peer review system.
- 8. Reviewing reports of peer review panels and making recommendations for research grants and fellowships.
- 9. Developing and providing oversight regarding mechanisms for the dissemination of research results.

This FOA covers the biomedical research grant programs included in subsections 2.1, 2.2, and 2.3.

#### 2.1. William B. "Bill" Bankhead, Jr., and David Coley Cancer Research Program

The William B. "Bill" Bankhead, Jr., and David Coley Cancer Research Program (Bankhead-Coley) is established in section 381.922, Florida Statutes. As described in statute, the program's purpose is to advance progress toward cures for cancer through grants awarded through a peer-reviewed, competitive process. The program provides grants for cancer research to further the search for cures for cancer, by pursuing the following goals:

- Significantly expanding cancer research capacity in Florida.
- Improving both research and treatment through greater participation in clinical trials networks.
- Reducing the impact of cancer on disparate groups.

#### 2.2. James and Esther King Biomedical Research Program

The James and Esther King Biomedical Research Program (James and Esther King Program) is established in section 215.5602, Florida Statutes. The purpose of the program is to support research initiatives that address the health care problems of Floridians in the areas of tobaccorelated cancer, cardiovascular disease, stroke, and pulmonary disease, by pursuing the goals to:

- Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease.
- Expand the foundation of biomedical knowledge relating to the prevention, diagnosis, treatment, and cure of diseases related to tobacco use, including cancer, cardiovascular disease, stroke, and pulmonary disease.
- Improve the quality of the state's academic health centers by bringing the advances of biomedical research into the training of physicians and other health care providers.
- Increase the state's per capita funding for research by undertaking new initiatives in public health and biomedical research that will attract additional funding from outside the state.
- Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

#### 2.3. Live Like Bella Pediatric Cancer Research Institute

The Live Like Bella Pediatric Cancer Research Initiative (Bella Initiative) is established in section 381.922, Florida Statutes. The Bella Initiative's statutory purpose is to advance progress toward curing pediatric cancer through grants awarded through a peer-reviewed, competitive process. The Bella Initiative provides grants for research to further the search for cures for pediatric cancer, by pursuing goals to:

- Significantly expand pediatric cancer research capacity in Florida.
- Improve both research and treatment through greater pediatric enrollment in clinical trials networks.
- Reduce the impact and burden of pediatric cancer on Floridians.

#### 3. RESEARCH FOCUS

All applicants must clearly demonstrate how the proposed project is relevant to cancer (Bankhead-Coley program), tobacco related diseases (James and Esther King Program) and pediatric cancer (Bankhead-Coley program and Bella Initiative). Proposals that do not or cannot demonstrate a close relationship with advancing progress toward cures for cancer or that endeavor to dramatically improve cancer morbidity and mortality will not be funded.

Applications submitted in response to this FOA must be responsive to one of the following areas of focus. Efforts to foster collaborations among institutions, researchers, and community practitioners should be included, when possible. Preference will be given to applications that address at least one of the cancers listed in the <u>Research Priorities</u> section of this FOA.

- 1. **Prevention and Treatment:** Research with a focus on prevention and improved treatment or care delivery that contributes to a reduction in deaths in at least one of the cancers listed in the Research Priorities section of this FOA.
- 2. **Screening:** Research that improves screening accuracy and/or detection of high-risk subgroups or improves implementation of a cancer screening program that results in an

- increase in early detection or prevention of at least one of the cancers listed in the Research Priorities section of this FOA.
- 3. **Obesity:** Research that enhances understanding of the relationship between obesity, healthy weight, and at least one of the cancers listed in the <u>Research Priorities</u> section of this FOA.
- 4. Treatment-Related Morbidities: Research that expands upon existing research and improves the scientific understanding of causes and subsequent impact of cancer/cancer-treatment related morbidities in other systems (e.g., cardiovascular, pulmonary, endocrine, lymphatic, central nervous system, reproductive, and developmental).
- 5. **Technology Transfer Feasibility (TTF):** Feasibility studies support technology transfer activities for promising research discoveries that could lead to innovations in the prevention, diagnosis, treatment, and/or cure of cancer and strengthen a project's economic feasibility and commercialization prospects. The primary objective is to assist investigators in moving promising research findings toward commercialization. This FOA offers early-stage funding to develop intellectual property and improve its commercial potential and competitiveness for further development activities, including company formation or partnering with private interests. Projects should be designed to establish the technical/scientific merit and feasibility needed to attract commercial interest. There is no requirement for the participation of a small business partner.

Example projects appropriate for the TTF submissions include:

- a. Preliminary animal model projects necessary to advance the research toward commercial viability.
- b. Developing and/or improving biomedical equipment use in the prevention, diagnosis, and treatment of cancer. Developing and/or improving assays useful in the prevention, diagnosis, and treatment of cancer.
- c. Developing new therapies and drugs for cancer.
- d. Developing methods, materials, models, or simulations necessary for translating research findings into standard practices for the prevention, diagnosis, and treatment of cancer.

Eligible projects must satisfy the following requirements:

- a. The technology/invention is protected or patentable.
- b. A patent search has been completed with no identical inventions found.
- c. A literature search has been completed and returned showing no identical published research.
- d. The technology/invention is free from prior disclosure(s) that would bar patentability.
- e. The technology/invention is free from any conflicting prior rights.
- f. The technology/invention is at a proof-of-concept stage.
- g. The technology/invention is the subject of ongoing and proactive research by a scientist.

- h. Potential products or services from the technology/invention meet or address an identifiable market need.
- 6. **Investigational New Drug or Investigational Device Exemption:** Research that supports the development of Investigational New Drug and Investigational Device Exemption applications to the United States Food and Drug Administration as part of an application for marketing. The intent is to support promising new drug discovery and commercialization of new drugs.

#### 4. RESEARCH PRIORITIES

To balance the number of grants awarded across research areas, the Department will prioritize applications that address the following:

- 1. Reduction of mortality and morbidity
- 2. Improved screening accuracy and detection.
- 3. Resistance to front-line treatments in recurrent disease in the five cancers listed below.
- 4. Research focused on sarcomas, or leukemia and other blood cancers.
- 5. Prevention and treatment research evaluating programs for tobacco use reduction and prevention (James and Esther King Program).
- 6. Research focused on the biologic mechanisms of use of electronic cigarettes, transition from combustible tobacco to electronic cigarettes, relationship between electronic cigarette use and different cancers, effects of electronic cigarette use in individuals treated for cancer, and intervention to reduce or prevent electronic cigarette use. (James and Esther King Program).
- 7. Examine the relationship between obesity and cancer, cancer treatment responsiveness, and cancer treatment-related morbidities. Applications related to other areas described in the FOA will be considered, but not at the same level of priority.

Preference will be given to applications that address at least one of the following:

- 1. Lung cancer
- 2. Breast cancer
- 3. Prostate cancer
- 4. Colon cancer
- 5. Melanoma
- 6. Pediatric-specific cancers

#### 5. GRANT CATEGORIES

Applications in response to this FOA must align to a grant category from the tables below (depending on the grant program) to pursue an area of focus from the <u>Research Focus</u> section of this FOA. Applications for research infrastructure grants that are reviewed and assigned exceptional scientific merit will be considered for preferential funding. Refer to the <u>Funding Information</u> section of this FOA for the maximum funding available per grant category.

#### **Grant Category Descriptions**

- 1. Bridge: The intent of this grant mechanism is to provide interim support for promising investigator-initiated research projects that have been highly rated by national panels of peer reviewers in recent federal competitions but were not funded due to budgetary constraints. In the case of this competition, no more than 18 months may pass between having received a funding decision by a federal agency and submission of an application to the Bankhead-Coley program. Allowable federal competitions include but are not limited to those conducted by the National Institutes of Health (NIH), the Department of Defense Congressionally Directed Medical Research Programs, the National Science Foundation, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the United States Food and Drug Administration. To be eligible, applicants must have submitted a multi-year, investigator-initiated research application to a federal agency (such as an NIH R type). The applicant must have received a peerreview summary statement indicating high scientific merit. For purposes of this competition, "high scientific merit" is a percentile ranking within five percentile points of the respective federal funding stream's pay line or a score of two or better for federal funding streams that do not provide a percentile rank with peer-review results.
- 2. Clinical Trials or Socio-Behavioral Interventions: Clinical research means research that prospectively gathers evidence of the benefits and harms of various treatment/intervention options for cancer, directly involves a person or group of people, or uses materials from humans, such as their behavior or collecting samples of their tissue. Applications in this area can include trials of new medications, trials of novel medication combinations, social behavioral health interventions, or health care delivery comparisons. Research can also include a focus on observational studies.
- 3. Discovery Science: Discovery science means fundamental theoretical or experimental investigative research to advance knowledge without a specifically envisaged or immediately practical application. Directed to understanding the events related to the development or prevention of tobacco-related diseases (James and Esther King Program) and cancer at the molecular, cellular, and organismic levels, as well as the discovery and development of new drugs or therapies. This section includes studies on basic biology of e-cigarettes. Applications under this mechanism can include observational or cross-sectional studies not involving a clinical trial. Outcome measures can be self-reported, observational, behavioral, biologic, or genetic.
- 4. Emerging Therapeutics and Technologies: This grant category supports research on emerging therapeutics and technologies used in the diagnosis and treatment of cancer and tobacco-related diseases. Examples include but are not limited to personalized/precision medicine therapies, immunotherapy, gene therapy, repurposing of previously used medications, use of artificial intelligence (AI) in diagnosis and treatment, and comparative effectiveness trials of emerging treatments. Studies focused on innovations in diagnosis and treatment of cancer and tobacco-related morbidities (James and Esther King Program) also fall under this mechanism.
- **5. Equipment:** The solicitation is for infrastructure/resources to augment research equipment that advances the current and future cancer research capability. The

- expectation is that new equipment will be shared with other researchers as appropriate to support collaborative efforts. Reporting on the role of equipment in research studies will be required.
- 6. Multicenter Clinical Trials (Bella Initiative only): Funding from this grant category for multicenter clinical trials is intended to support evaluation of the safety, efficacy, and effectiveness (Phase I, II, III, and IV) of repurposed or new and innovative drugs and other treatments for pediatric cancers. Trials may include randomized clinical trials or innovative applications of precision medicine strategies using targeted therapies. Multicenter clinical trials need to involve investigators from at least two distinct research/clinical facilities in Florida and must be implemented in two or more locations in Florida.
- 7. New Investigator Research (NIR): The intent of the NIR grant category is to foster development of new investigators so they may undertake independent research that is competitive for national research funding. New investigators must have been full-time faculty for no more than six years and must work under the mentorship of a senior investigator.
- 8. High-Risk, High-Reward Clinical Research: Research in this mechanism of support test innovative therapeutic approaches or novel treatment modalities with transformative potential but substantial uncertainty regarding feasibility, safety, or efficacy. These include first-in-human studies, unconventional drug repurposing, or interventions targeting previously undruggable pathways. The high-risk component encompasses potential trial failure, unexpected adverse events, or negative results that could redirect research programs. The high-reward potential includes paradigm-shifting breakthroughs, dramatic clinical improvements, or validation of novel biomarkers that revolutionize personalized medicine.
- 9. High-Risk, High-Reward Discovery Science: Research in this mechanism of support pursues bold, unconventional hypotheses or cutting-edge methodologies to explore uncharted biological territories relevant to tobacco-related diseases and cancer. This research challenges existing paradigms, investigates counterintuitive phenomena, or develops innovative approaches that may appear technically unfeasible. The high-risk nature stems from possibilities that novel hypotheses prove incorrect or new methods fail to yield interpretable data. The high-reward potential includes groundbreaking discoveries that fundamentally alter disease understanding, identify new therapeutic targets, or elucidate previously unknown pathways spawning multiple research directions.
- 10. Non-Typical Clinical Trials/Socio-Behavioral Research: Research in this mechanism of support encompasses studies using innovative methodologies beyond traditional randomized controlled trials, including adaptive designs, observational studies, behavioral interventions, implementation science, digital health approaches, and research examining psychosocial factors affecting prevention, treatment, and outcomes.
- **11. Research Infrastructure:** Eligible organizations may submit an infrastructure application in at least one of the following six areas: tissue banking, bioinformatics, genomics, diagnostic imaging, disproportionately impacted individuals, or quality indicator systems, as described on the following pages. The Department is particularly

interested in research involving quality indicator systems, when this is linked with other priorities, such as increasing the number of Florida research networks, external funding for research infrastructure, and large-scale projects, including but not limited to National Cancer Institute grants. Organizations will only be permitted to be the lead on one application but may be collaborators on applications submitted by other organizations. When organizations collaborate on more than one infrastructure application, they need to describe how the projects are different and do not overlap.

The expectation is that infrastructure improvements, where practical, will be made available to and used by researchers throughout Florida. Projects need to demonstrate institutional collaboration and statewide research networks in the pursuit of a research question or development of infrastructure. In addition, projects need to provide a quantitative method to evaluate the use of infrastructure resulting from this grant. For example, the investigator could measure the number of patients screened from a medical imaging device or the number of researchers external to the project who were provided with tissue samples.

#### Applications must describe:

- a. A plan for providing access to the funded infrastructure.
- b. A scientific advisory process involving researchers from at least four universities and/or research institutions.
- c. A community advisory process that represents the perspective of participants in research.

Applications may include support to address ethical and legal issues in the research. The solicitation is limited to proposals that will improve infrastructure/resources in the areas of tissue banking, bioinformatics, genomics, diagnostic imaging, and quality indicator systems.

a. **Tissue banking:** Research Infrastructure encompasses infrastructure/resources to expand procurement of tissue samples for research in cancer; expand the intake, storage, and analysis of specimens; and expand the distribution of samples for research. The solicitation seeks applications for infrastructure/resources required to create sustainable programs that increase the number of samples from healthy persons and from under-represented groups. The expectation is that funded projects will result in the procurement of a substantial number of samples by the end of the grant period, as well as a sustainable program for ongoing collection of samples from healthy people. In addition to expanding procurement through outreach and recruiting, funds may be used to expand existing infrastructure and software for intake, storage, and analysis. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and timeframes for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure. Projects may include infrastructure and programs to improve dissemination and sharing of tissue samples. The expectation is that tissue samples will be shared with any university or research institution in Florida, and that there will be a significant increase in the sharing of samples by the end of a project.

- b. Bioinformatics: Research Infrastructure can also include applications to expand existing infrastructure/resources for analysis of biomedical data, including genomic and proteomic information and the study of biological systems most relevant to cancer. Projects may include improving algorithms, databases, and modeling of biological phenomena; purchase of equipment and software; and support for the expansion of cross-disciplinary research teams. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and timeframes for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure. Projects may include but are not limited to expanding the ability to analyze very large data sets; the identification of tissue-specific biomarkers brought on by cancer; or improvements in ways of automating clinical imaging.
- c. Medical imaging: Research Infrastructure can also include expand existing infrastructure that improves the quality, speed, and accuracy of medical imaging or develops processes that measure the effectiveness of imaging technologies. Projects may include but are not limited to improvements in screening for lung and breast cancer, or research examining the correlation between the expanded use of imaging technologies and health outcomes. Projects may include improvements to software and equipment. The expectation is that projects will include sustainable ongoing mechanisms to improve the sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and timeframes for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.
- d. Genomics: Expanding research infrastructure also may comprise areas of functional genomics, genomic biomarkers, epigenetics, next-generation sequencing, miRNA and non-coding RNA, qPCR, proteomics, and proteome analysis including chromatography or mass spectroscopy. Funds are intended to be used to upgrade software and equipment that will make organizations competitive for additional funding and serve as a national resource. The expectation is that projects will include sustainable ongoing mechanisms to improve the sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and timeframes for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.
- e. Quality indicator systems: Research Infrastructure may also include support for a continuous comprehensive quality indicator system associated with improved cancer treatment outcomes. Research Infrastructure supports projects that create sustainable ongoing systems to collect quantitative data about treatment outcomes and compare them with national outcomes or treatment processes and compare them with evidence-based standards, including consensus standards, or other practice standards such as emerging findings in the research literature. The expectation is that the organization will publish treatment outcomes at least annually in a prominent place on the

organization's website and publish descriptions of how the organization is using the information obtained through the collection of quality indicators to improve care. The expectation is that projects will include sustainable ongoing mechanisms to improve the sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and timeframes for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

#### 6. FUNDING INFORMATION

Applicants must request funding in the preceding grant categories to pursue research in the areas of focus outlined in the <u>Research Focus</u> section of this FOA. Preference will be given to applications that address the priorities listed in the <u>Research Priorities</u> section of this FOA. For more information about the types of grants listed below, please see the descriptions in the <u>Grant Categories</u> section of this FOA.

Table 1. Bankhead-Coley / James and Esther King Program Grant Categories, Maximum Amounts, and Maximum Duration

Bankhead-Coley / James and Esther King Program		
Grant Category	Maximum Amount (Including direct and indirect costs)	Maximum Duration
Clinical Trials/Socio-Behavioral Interventions	\$1,500,000	48 Months
High-Risk, High-Reward Clinical Research	\$750,000	48 Months
Discovery Science	\$600,000	36 Months
Emerging Therapeutics and Technologies	\$600,000	36 Months
High-Risk, High-Reward Discovery Science	\$300,000	36 Months
New Investigator Research (NIR)	\$300,000	36 months
Non-typical Clinical Trials/Socio- Behavioral Research	\$250,000	36 months
Research Infrastructure	\$1,500,000	36 Months
Equipment	\$100,000	12 months
Bridge	\$100,000	6 months

Table 2. Bella Initiative Grant Categories, Maximum Amounts, and Maximum Duration

Bella Initiative			
Grant Category	Maximum Amount (Including direct and indirect costs)	Maximum Duration	
High-Risk, High-Reward Clinical Trials	\$300,000	48 months	
Multicenter ClinicalTrials	\$900,000	48 months	
Discovery Science	\$250,000	36 months	
Emerging Therapeutics and Technologies	\$600,000	36 months	
High-Risk, High-Reward Discovery Science	\$125,000	36 months	
New Investigator Research (NIR)	\$300,000	36 months	
Non-Typical Clinical Trials/ Socio- Behavioral Research	\$250,000	36 months	
Equipment	\$100,000	12 months	
Bridge	\$100,000	6 months	

Applications for research infrastructure grants that are reviewed and assigned exceptional scientific merit will be considered for preferential funding. Award allocations will be based on the scope of the project and dependent on funds available, subject to the annual appropriation of funds by the Florida Legislature and spending authority granted to the Department.

#### 7. ELIGIBILITY

#### 7.1 Applicants

According to sections 215.5602(5)(a) and 381.922(3)(a), Florida Statutes, applications for biomedical research funding may be submitted by **any Florida-based universities or established research institutes**. Additionally, to be considered eligible, all of the following guidelines must be met. **Grant applications failing to meet the eligibility requirements will be rejected.** 

- All grant-funded activities must take place in Florida. All work (effort) must occur, and funds must be spent, in Florida at the applicant organization and any collaborating entities. However, the Department may make exceptions if the service is essential and only provided outside Florida, and if the amount is less than 10 percent of the total award.
- 2. Subcontracts must be described in the Public Health Research Program Budget Template (Attachment V) and are subject to pre-approval. The Budget Narrative must justify the purpose of the subcontract, whether this is the only vendor that can perform the services, regardless of if they are in-state or out-of-state.
- 3. Each project proposal must identify a Corresponding Principal Investigator (PI). The PI is the individual, designated by the Applicant, who is legally responsible to direct the

project and is accountable for the project's scientific and technical direction as well as the proper conduct of the project. There may be multiple PIs (called Co-PIs) on a project, but there must be only one designated PI.

- a. The PI must be an employee of the Applicant organization/entity and meet that institution's criteria for serving as a PI in addition to meeting the eligibility requirements listed in this FOA.
- b. The PI must be a U.S. citizen or permanent resident; unauthorized aliens shall not be employed pursuant to §274A(e) of the Immigration and Naturalization Act (8 U.S.C. 1324a), section 101 of the Immigration Reform and Control Act of 1986, and Florida Executive Order 11-02. Non-U.S. citizens can serve as Collaborators or members of a research team.
- c. The PI may serve as Co-PI or other role on other applications, provided they are not over-committed. The Corresponding Principal Investigator shall not:
  - Apply for the same research project for which he or she was a
    previously funded grant recipient. The aims and experiments in the new
    proposal must be significantly different from any previously funded
    grants.
  - ii. Submit the same project/research that is also being submitted by another investigator regardless of the grant mechanism.
  - iii. Submit duplicate projects or projects with significant scientific or financial overlap during the same competition year.
- 4. Applicants must ensure that their proposed project does not duplicate or significantly overlap, scientifically or financially, with other projects in which they or any key personnel are involved. Overlap, whether scientific or financial, or commitment of a project member's effort greater than 100% is prohibited.

#### 7.2. Guidelines for BRAC Member Participation

BRAC has statutory conflict of interest obligations regarding the participation of its members in grant applications.

#### BRAC members shall not:

- 1. Receive any form of financial compensation from Bankhead-Coley, James and Esther King Program, or Bella Initiative grant awards.
- 2. Participate in any named role on a proposed Bankhead-Coley, James and Esther King Program, or Bella Initiative grant projects in this FOA.
- 3. Advise applicants regarding the preparation of a specific grant application for a Bankhead-Coley, James and Esther King Program, or Bella Initiative grant awards.
- 4. Answer any programmatic questions (including those related to eligibility, the contents of the FOA, competition procedures, etc.).
- 5. Violate any provision of Chapter 112, Part III, Florida Statutes.

BRAC members <u>may</u> provide, and sign letters of assurance/support or cover pages submitted as part of the application in cases in which doing so is part of their official duties at the applicant organization.

Violations of these restrictions may result in the disqualification of an applicant for this competition.

#### 8. KEY DATES

Please refer to the table below for a schedule of key grant-related dates.

**Table 5. Schedule of Important Dates** 

Activity	Date	Key Information
FOA Announced	Anticipated: November 20, 2025	Located on the Biomedical Research Program's Funding Opportunity Announcements web page on the Department's website.
Letter of Intent Opens ( <i>Required</i> )	By 5:00 p.m., ET on December 2, 2025	Letter of Intent must be submitted in the online system located on the Biomedical Research Program's Funding Opportunities web page. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
Emailed Questions Accepted	Due by: 5:00 p.m. ET on November 30, 2025	Email questions to: Research@flhealth.gov
Q&A Posted Online (answers to emailed questions)	By December 1, 2025	Questions and answers will be published on the Biomedical Research Program's Funding Opportunity Announcements web page.
Letter of Intent Due (Required)	Due by: 12:00 p.m. ET on December 16, 2025	Letter of Intent must be submitted in the online system accessible from the Biomedical Research Program's Funding Opportunity Announcements web page. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
Application Opens	Anticipated: December 22, 2025	Applications must be submitted in the online system located on the Biomedical Research Program's Funding Opportunity  Announcements web page.
Applications Due	Submissions due by: 12:00 p.m. ET on January 12, 2026	Applications must be submitted before the deadline. Applications being edited will not be accepted after the deadline.

Any changes to the schedule will be posted to the Biomedical Research Program's <u>Funding Opportunity Announcements</u> web page. Applicants should monitor the website for changes and announcements.

## 9. Institutional Approvals

If selected for funding, the grantee must submit to the Department, <u>within five business</u> <u>days</u> of executing the Grant Agreement, proof of submission to the appropriate institutional review bodies, along with any applicable protocols and consent forms. This includes, but is not limited to:

- Institutional Review Board (IRB) approval for projects involving human subjects
- Institutional Animal Care and Use Committee (IACUC) approval for projects involving vertebrate animals
- Institutional Biosafety Committee (IBC) approval for projects involving recombinant DNA or stem cells
- Radiation Safety Committee (RSC) for projects involving radiation

All required institutional authorizations must be addressed based on the specific activities of the grant project.

Projects that include research participant incentives in their budgets must obtain approval from an **Institutional Review Board (IRB)** accredited by the **Association for the Accreditation of Human Research Protection Programs (AAHRPP)** or another accrediting body approved by the Department.

If the proposal is selected for Department funding, the grantee must submit the original IRB-approved protocol and consent forms to the Department prior to the distribution of any incentives. These documents will be retained in the Department's grant management folder.

#### 10. PROGRAM GUIDELINES

#### 10.1. Budget Guidelines

Award allocations will be based on the scope of the project and dependent on funds available, subject to the annual appropriation of funds, and approval of spending authority, by the Florida Legislature to the Department. All costs must be allowable, reasonable, and necessary for the successful completion of the program. Costs must be specifically related to the services provided and comply with state and federal expenditure laws, rules and regulations. Costs that do not meet these criteria are disallowed.

In preparing the requested budget, applicants should be aware of the provisions in subsections 10.2.1. through 10.2.4 of this FOA.

#### 10.1.1. Allowed Direct Costs

Allowed direct cost expenses must be directly related to the project and may include:

- 1. Salaries, including up to a three percent (3%) increase per year.
- Background screening: If Level II background screening is required (e.g., for personnel who will have direct interaction with vulnerable populations such as minors, elderly individuals, or individuals with disabilities), the associated costs should be included under the "Other Expenses" category in the budget.

- 3. Tuition: To assure that the tuition waiver or reimbursement is related to the research project, a course description or class schedule must be submitted with the quarterly invoice that includes the tuition waiver or expenditure. Tuition waivers or support should be included in the approved Public Health Research Program Budget Template and the purpose of the tuition support must be included in the final Budget Narrative. Submitting class schedule or attestation of verification by the Principal Investigator with quarterly invoices is required for payment.
- 4. Fringe benefits: Benefits should be calculated based on institutional policy and must be applied consistently for all personnel listed in the budget. This may include costs such as health insurance, retirement contributions, FICA, workers' compensation, and other employee-related benefits. Applicants should provide a breakdown of the fringe benefit rate(s) used and the total cost per individual and ensure that fringe costs are clearly aligned with salary requests. All fringe benefit calculations must be reasonable, allocable, and conform to the organization's approved accounting practices. If different rates apply for different categories of employees (e.g., faculty vs. staff vs. part-time), these distinctions should be clearly identified and justified in the budget narrative.
- 5. Supplies: Supplies should include consumable items necessary to carry out the proposed research project. These may include, but are not limited to, laboratory materials (e.g., chemicals, reagents, pipettes), glassware, small laboratory equipment (typically with a unit cost under \$5,000), computer supplies, and other expendable items. All supply costs must be clearly itemized, reasonable, and directly related to the activities described in the Research Plan. The budget narrative should provide sufficient detail to justify the quantity, purpose, and estimated cost of each supply category. Note: General office supplies, administrative support materials, or items considered part of normal institutional overhead are typically not allowable unless explicitly justified as essential to the scientific aims of the project.
- 6. Equipment: Equipment costs should include the purchase, installation, or improvement of durable items necessary for the successful completion of the proposed research. For the purposes of this FOA, "equipment" is defined as any tangible, non-expendable property that: (1) Has a purchase price of more than \$5,000, and (2) Has an expected useful life of more than one year. Examples of allowable equipment include but are not limited to: Computed Tomography (CT) scanners, Magnetic Resonance Imaging (MRI) systems, Other advanced imaging systems or diagnostic equipment, Significant upgrades or improvements to existing equipment that extend its useful life or enhance its capabilities. All equipment requests must be clearly justified in the budget narrative. Justifications should explain how the equipment is essential to the research objectives and why existing institutional resources are insufficient. If equipment will be shared among multiple projects or investigators, applicants should describe the sharing plan and anticipated usage. Routine maintenance, service contracts, or minor repairs should be included under "Other Expenses," unless they are part of an initial equipment purchase package. If multiple units of the same item (e.g., laptops, tablets, or similar devices) are purchased together on a single invoice and the total combined cost exceeds \$5,000, the purchase may be considered equipment under this FOA, even if the individual items fall below the \$5,000 threshold. Applicants should consult their institutional policies for proper classification and ensure consistency with federal cost

- principles. Reminder: Equipment purchases must comply with institutional policies and federal cost principles (e.g., 2 CFR §200.313), if applicable.
- 7. Lab services: Lab services include the cost of external laboratory testing or analyses that are essential to the proposed research and cannot be performed internally by the applicant's institution. This may involve specimen processing, specialized assays, genomic or proteomic analyses, histology, pathology, or other diagnostic or analytical services. All lab service costs must be directly tied to the research objectives, reasonable, and justified in the budget narrative. If third-party labs are used, costs should be supported by institutional procurement policies or documented vendor quotes.
- 8. Consultant costs, **provided they do not exceed 10 percent of the total budget**: Consultant costs cover fees paid to individuals who are not employees of the applicant organization but are engaged to provide specific expertise or advisory services relevant to the research. Consultants may include biostatisticians, clinical experts, or subject matter specialists whose contributions are essential to the project. These costs must be based on a reasonable hourly or daily rate and supported by a detailed scope of work, justification of qualifications, and a letter of commitment. The total consultant costs must not exceed 10 percent of the total proposed budget.
- 9. Patient-care costs: Patient-care costs refer to clinical services provided to research participants as part of the approved study protocol. These costs may include medical tests, imaging, procedures, and clinical visits that are required by the research but are not covered by insurance or considered part of routine care. Only those costs directly attributable to research activities are allowable. A detailed justification is required, including a clear distinction between standard-of-care and research-specific services, and compliance with institutional and federal billing policies must be maintained.
- 10. Animal-care costs: Animal-care costs include all expenses related to the acquisition, housing, and veterinary care of live vertebrate animals used in the research. This may encompass per diem rates for housing, feeding, veterinary oversight, and facility fees. The proposed animal-care costs must be consistent with institutional animal care policies and approved Institutional Animal Care and Use Committee (IACUC) protocols. If animal housing or services will occur at another institution, inter-institutional agreements and appropriate documentation should be in place.
- 11. Committee fees for IRB or Institutional Animal Care and Use: Committee fees are those charged by Institutional Review Boards (IRBs) and Institutional Animal Care and Use Committees (IACUCs) for the review and oversight of research protocols involving human subjects or animals, respectively. These may include initial and continuing review fees, protocol amendments, or administrative processing charges, particularly when using independent or commercial IRBs. All committee fees must be justified and based on the anticipated timeline and regulatory needs of the proposed research activities
- 12. Consortium or contractual costs: This category includes costs related to formal partnerships with other institutions or organizations that will carry out a substantive portion of the research. These arrangements may involve universities, hospitals, community-based organizations, or research centers serving as subrecipients or contractors. Each consortium or contractual relationship must be supported by a detailed budget, budget justification, scope of work, and a letter of commitment from the

- collaborating entity. The applicant institution remains responsible for ensuring compliance with grant requirements and for monitoring all subrecipient activities.
- 13. Fees to obtain data from the Florida Cancer Registry Data System and Department's Bureau of Vital Statistics: These are direct costs associated with accessing data from the Florida Cancer Data System (FCDS) and the Florida Office of Vital Statistics, including vital records or cancer incidence data necessary to support the research. Applicants should identify the type of data requested, the estimated costs based on current data access fees, and how the data will be used to address the research aims. Documentation from the data source indicating fees or approval to access may be included in the budget justification.
- 14. Domestic travel: Travel will be reimbursed at no more than the state of Florida travel reimbursement rates. Current Florida reimbursement rates can be found in section 112.061, Florida Statutes, and in the Reference Guide for State Expenditures. In order to implement appropriations in the General Appropriations Act for state travel and notwithstanding section 112.061, Florida Statutes, costs for lodging associated with a meeting, conference, or convention organized or sponsored in whole or in part by a state agency or the judicial branch may not exceed \$225 per day. If awarded, grantees must submit a travel authorization form and travel reimbursement voucher form in every quarter in which they will charge travel to their grant budgets. Travel is only approved within the United States (U.S.). The State of Florida Authorization to Incur Travel Expenses and the State of Florida Voucher for Reimbursement of Travel Expenses forms must be used for all travel-related expenses unless the research institution's travel voucher/expenditure form has received prior approval from the Florida Department of Financial Services (DFS). Supporting documentation is required for all travel-related expenses e.g., receipts for flight, hotel (up to \$225/night), parking, rental car, gas, ground transportation, as well as registration, meeting agenda/schedule, and copy of any presentation(s) made. Travel forms and guidance are available on Biomedical Research Program's Grant Management Forms and Resources web page.
- 15. Incentives: Research participant incentives can include cash, check, or gift card. Gift cards should not be purchased in bulk as tracking and inventory control can be difficult. Gift cards should be purchased on an "as needed" basis. Inventory control methods must be maintained for any existing or remaining gift card stock. If awarded, the original approved IRB protocol and consent form must be submitted to the Department before any participant incentive charges may be made to the grant. Each grant agreement executed will reference the approved IRB protocol in the method of payment section of each grant agreement.

#### 10.1.2. Maximum Annual Base Salary Calculations

Grant funds may be used to pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. The maximum annual base salary used in calculating these payments must not exceed the Executive Level II annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See the <a href="Definitions">Definitions</a> section of this FOA for more information about the Federal Executive Pay Scale. This salary cap excludes fringe benefits, facilities, and administrative (finance and accounting) expenses, and any income that an individual may be permitted to earn outside of the duties to

the applicant organization. This provision is consistent with the NIH salary limitations on grants and cooperative agreements.

#### 10.1.3. Allowed Indirect Costs

Indirect costs, also commonly referred to as **Facilities and Administrative (F&A) costs**, **Finance and Accounting costs**, or **administrative overhead**, are expenses incurred by the institution that are not directly attributable to a specific research project but are necessary for the general operation and support of research activities. These costs typically include, but are not limited to, expenses related to building maintenance, utilities, administrative salaries, accounting services, library services, and institutional compliance activities such as safety and regulatory oversight.

Examples of indirect costs include:

- Facility maintenance (e.g., utilities, janitorial services, building repairs)
- Administrative personnel salaries (e.g., human resources, grant administration staff)
- Financial management and accounting services
- Compliance and regulatory costs (e.g., institutional review board administration, environmental health and safety)
- General office supplies and services that support the institution broadly rather than a single project

For this Funding Opportunity Announcement, **indirect costs may not exceed 15% of the total direct costs requested**. Applicants must calculate IDC based on their institution's approved indirect cost rate or, if no negotiated rate exists, on the 15% maximum allowable. This cap is intended to ensure that a reasonable portion of funds supports administrative infrastructure while maximizing resources directly applied to research activities.

Applicants should provide:

- (1) The **indirect cost rate** being applied and its basis (e.g., federally negotiated rate agreement or institutional policy),
- (2) A clear calculation showing how the IDC amount was derived from the direct costs, and
- (3) Justification if the institution's federally negotiated rate exceeds the 15% limit, noting that costs above 15% will not be reimbursed under this FOA.

Institutions without a negotiated indirect cost rate may request the maximum 15% as a de minimis rate in accordance with federal guidance (2 CFR §200.414(f)). This indirect cost cap applies only to the portion of the budget categorized as direct costs; any subcontract or consortium indirect costs should be detailed separately, with supporting documentation provided as needed.

Adherence to this indirect cost limit is mandatory. Proposals exceeding the 15% IDC cap will be subject to budget adjustments during the review process or post-award negotiation to bring indirect costs within allowable limits.

#### 10.1.4. Disallowed Costs

All direct costs must be specifically and directly related and allocated to the project, necessary for the project's completion, adequately justified, and made during the active grant period. Any

other costs are disallowed. Additionally, the following items shall NOT be paid for with grant funds:

- 1. Florida Department of Health personnel salary
- 2. Construction, renovation, or remodeling
- 3. International travel (including Canada)
- 4. Vehicles
- 5. Entertainment
- 6. Employment subsidies
- 7. Dues/Membership fees
- 8. Lobbying
- 9. Meals/Food (other than as part of travel costs)
- 10. Malpractice insurance premiums
- 11. Expenditures related to legal services, business filing fees, or other costs for visas, green card or similar processing fees

#### 10.2. Overlap Limits

Applicants must ensure that their proposed project does not duplicate or significantly overlap, scientifically or financially, with other projects in which they or any key personnel are involved. Overlap, whether scientific or financial, or commitment of a project member's effort greater than 100%, is prohibited.

#### 10.3. Protecting Intellectual Property

Submitted materials are subject to the provisions of Article I, Section 24, Florida Constitution and Chapter 119, Florida Statutes, Florida's public records law. These laws grant the right to any person to inspect any public record. There are some documents and information that are exempt from the public records laws. All application materials are public record unless the applicant can show how they are exempt.

Applicants are strongly discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. If the application contains information that the applicant believes constitutes trade secrets, intellectual property, proprietary information, or information protected by a specific statutory exemption, it should be limited to the Specific Aims section of this proposal. The applicant must clearly identify the confidential information with [brackets] and a footnote that specifies the law that makes the document or information exempt from the public records laws.

If a public records request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may substantiate and defend the claim. The Department will not provide legal representation to assert a confidentiality claim.

#### 11. RESPONDING TO THIS FOA

#### 11.1 Application Guidelines

The following application guidelines must be followed:

1. Applicants must register and submit an application through the online system accessible from the Biomedical Research Program's <a href="Funding Opportunity Announcements">Funding Opportunity Announcements</a> web page.

- 2. Application materials not submitted in the specified manner and in the specified format will be disqualified from competition.
- Required signature pages such as budgets and letters of support, must be included in the appropriate section of the application as indicated in the online instructions. Online applications without scanned copies of these pages will be disqualified. Electronic signatures such as those generated by a certified process like Adobe sign are acceptable.
- 4. Other documentation and materials such as biographical sketches and other support must be converted to electronic format and placed in the appropriate section of the online application.
- 5. Peer reviewers evaluate only the materials in the application, and do not consider other sources of information.
- 6. The Department recommends that applications be submitted early. Applications submitted past the deadline will not be considered, regardless of the reason.
- 7. Submission of an application is considered an acceptance of the terms and conditions of this FOA.

#### 11.1.1. Duplicate Applications and Resubmission Policy

Eligible applicants can submit one application per project to the Bella Initiative, one application per project to the Bankhead-Coley program, and one application per project to the James and Esther King Program. Applications must be different. Applicants may not submit the same applications, or substantially similar applications, as determined by the Department, to the Bella Initiative, Bankhead-Coley program, and James and Esther King Program.

Applicants who submitted but were not funded in the previous fiscal year funding competition, may submit a revised application only one time. Applicants may submit either a new application or revised application from the previous fiscal year funding competition but cannot submit both.

Applicants can submit:

- 1. One new application to the Bankhead-Coley program or one revised application, but not both.
- 2. One new application to the James and Esther King Program or one revised application, but not both.
- 3. One new application to the Bella Initiative or one revised application, but not both.

Applicants cannot submit more than two applications or substantially similar applications to the same grant funding program.

#### 11.1.2. Changes to a Submitted Application

It is the responsibility of the applicant to ensure that a complete application is submitted before the date and time specified in Key Dates section of this FOA. The Department does not allow submitted application files or data to be replaced or changed after the submission deadline. This decision will help ensure no applicants receive an unfair advantage. Before submitting your application, please check it for completeness, accuracy, quality, and readability. This should

include verifying that all graphic elements, including tables, charts, and images are converted properly when saving the original documents in PDF format as required.

#### 11.1.3. Inclusion of Department Data

Applications for research that includes Department data must include a letter of support from the office that houses the data. For example, researchers conducting behavioral health research involving tobacco cessation and control data from the Department must include a letter of support from the Tobacco Free Florida program. Requests must include an overview of the data being requested from each data registry.

Following is the contact information for common Department data requests:

- 1. Bureau of Vital Statistics: Email VitalStats@flhealth.gov.
- 2. Florida Cancer Data System: Email Heather Lake-Burger at <u>Heather.Lake-Burger@flhealth.gov.</u>
- 3. Tobacco Free Florida Program: Email Contact@TobaccoFreeFlorida.com.

#### 11.2 Application Preparation

In preparing their application, applicants should be aware of the provisions in sections 11.2.1 and 11.2.2 of this FOA.

#### 11.2.1 Application Components

A complete grant application package must contain all required fields, including the components outlined below, in the online application accessible through the Biomedical Research Program's <u>Funding Opportunity Announcements</u> web page. Note: The online application will prompt applicants of required fields and character limits for each section.

**Table 6. Application Components** 

Components	Instructions
Letter of Intent	<b>Required.</b> Submit a Letter of Intent (LOI). Submission of an LOI is required <b>prior to the submission of an application</b> . For collaborative or consortium applications, the lead organization is required to submit the LOI.
General Project Information	<b>Required.</b> Identify general project information, including the applicant organization and the Corresponding Principal Investigator.
General Audience Abstract (3,500 maximum characters)	<b>Required.</b> Explain the proposed project in lay terms, including its relationship to the goals of the Florida Department of Health. This information must be included in the General Project Information section of the application.
Scientific Abstract (2,100 maximum characters)	<b>Required.</b> Provide the scientific description of the project. This description must be included in the General Project Information section of the application.
Health Impact (3,500 maximum	<b>Required.</b> Describe how the proposed project impacts the health of Floridians. For the purposes of this FOA, "health impact" means the ability

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characters)	of the research to reduce morbidity and mortality from cancer. Applications must describe how the results of the research can provide information and evidence for changes in policy, improve health service delivery and quality of care, or improve disease prevention through improvements in health literacy and changes in behavior within a certain amount of time. Applications must also consider possible long-range effects of applying knowledge gained in the research, or the ability of the research to support future research grant applications or publications or patents. Applicants will complete this in the General Project Information section of the application.
Cancer-	Required. Provide a clear explanation of how the project is related to
Relatedness (2,100 maximum characters)	cancer. This explanation must be included in the General Project Information section of the application.
Collaborator Information	Required. Identify all key personnel involved in the project.
Biographical Sketch (100 MB maximum file size)	<b>Required.</b> Upload bio-sketches of key personnel involved in the research. All bio-sketches must be uploaded as a single document in the format specified in the online system.
Consultants (100 MB maximum file size)	Required (if there are consultants). Upload letters from all consultants confirming their project roles, including the rate/charge for consulting services. Letters must be uploaded as a single document.
Specific Aims (6,800 maximum characters)	<b>Required.</b> Describe the specific aims including the significance, innovation, and approach of the project. Provide a bibliography of any references cited and list facilities and other resources.
Human Subjects	Required (if applicable). Describe protections for human subjects involved in the research. If human subjects will be involved at any time in the research, even if the project protocol has already received Institutional Review Board approval or is deemed exempt, the applicant must address all human subject questions in the online application. If all questions are not answered, the application will be disqualified.
Vertebrate Animals	Required (if applicable). Describe protections for animals involved in the research. If vertebrate animals will be used at any time in the research, the applicant must address all vertebrate animals' questions in the online application. If all questions are not answered, the application will be disqualified.
Recombinant DNA Molecules	<b>Required (if applicable).</b> Describe use of recombinant DNA molecules involved in the research.
Survey Instruments (100 MB maximum file size)	Required (if applicable). Survey Instruments must be uploaded as a single document. This means all questionnaires, interview guides, scales, or other data collection tools related to the project should be compiled into one file, rather than submitted as multiple separate files. The document should be clearly formatted, with each instrument properly labeled and organized in the order they will be used or referenced in the research. This ensures ease of review and helps maintain the integrity of the materials submitted. Acceptable file formats typically include PDF or Word documents, and the file should be free of password protection or editing

	restrictions.
Table, Image, or Graph (100 MB maximum file size)  Optional. Images, graphs, and figures may be included with the application; however, these cannot appear in the text of the application. Figure application in the section. Figure need to be included in the document. Upload a single document of images, graphs, and figures. There is no page limit on the number images, graphs, and figures.	
Budget Template (Budget Summary & Narrative) (100 MB maximum file size)	<ul> <li>Required. The budget must explain the planned spending. See appendix for a sample of the template. The budget template includes both the budget summary and budget narrative documents or forms referenced in this FOA.</li> <li>The budget summary provides a concise overview of the total funding requested, detailing major cost categories—such as personnel, equipment, supplies, and other expenses—necessary to complete the proposed research project.</li> <li>The budget narrative must provide a detailed explanation of how funds in each budget category will be spent for each year of project funding. It should include a written justification for the necessity and calculation of each budget item and demonstrate how the requested funds align with and support the goals and activities of the proposed research project.</li> <li>The budget template can be downloaded within the online application system. The completed budget template form must be uploaded as a single document. For applications involving collaborations with different universities or research institutions, the lead institution should complete the budget form and include collaborating institutions as a contractual expense.</li> </ul>
Letters of Support (100 MB maximum file size)	Required (if applicable). If applying for a grant involving Department of Health data, a signed letter of support must be uploaded for each dataset owned by the Department. Letters of support are not required for other types of research. Upload a single document in the appropriate upload field. There is no limit to the number of letters of support that may be submitted.
Work Plan (100 MB maximum file size)	Required. The Work Plan must include a clearly defined evaluation plan with measurable outcomes that align with the goals and objectives of the proposed research. Applicants should outline the specific activities, timelines, responsible personnel, and performance metrics that will be used to assess progress. The Work Plan should describe how success will be measured, including the tools and methods for data collection and analysis. Outcomes should be realistic, time-bound, and quantifiable wherever possible, and the plan should demonstrate how evaluation results will inform the ongoing development and impact of the project.

Applicants are discouraged from submitting information considered proprietary, unless it is deemed by the applicant to be essential for proper evaluation of the application. See the Requirements for Protecting Intellectual Property section of this FOA for more information.

#### 11.2.2. Letter of Intent

Submission of a Letter of Intent (LOI) is **required prior to submission of an application**. For collaborative applications, the lead organization is required to submit the LOI. Applications will not be accepted if the researcher has not submitted an LOI by the deadline listed the Key Dates section of this FOA. Researchers must apply under the same title that was specified in the LOI.

Prospective applicants must submit a letter of intent through the online system that includes the following information:

- Program name (James and Esther King Biomedical Research Program, Bankhead-Coley Cancer Research Program, or Live Like Bella Pediatric Cancer Research Initiative)
- 2. Name, address, telephone number, and email address of the Project Director or Corresponding Principal Investigator
- 3. Names of other research personnel
- 4. Lead institution
- 5. Collaborating institutions and collaborating research personnel, if any
- 6. Descriptive title of proposed research
- 7. Research priority
- 8. Grant category
- 9. General audience abstract (no more than 3,500 characters)
- 10. Keywords

#### 11.3. Application Submission

In preparing their application submission, applicants should be aware of the provisions in sections 11.3.1. through 11.3.3 of this FOA.

#### 11.3.1. Online Application Portal

The online system will be available to accept applications for this FOA on the date published in in the Key Dates section of this FOA.

To complete the online application process:

- Applicants must register to access the online application and forms. During
  registration, complete the brief project profile. Information entered into the
  registration fields will carry forward to the application. Registration will be
  acknowledged with an email message containing login instructions and a username
  and password.
- 2. Complete the online application form. Deviations may be grounds for the Biomedical Research Program to reject the entire application. Special formatting, scientific notation, pictures, and objects may be included in these documents. However, within the online application form fields (such as the Project Title, General Audience Abstract and the Scientific Abstract), use only conventional alphanumeric letters and numbers (i.e. ASCII text) with no drawings, special characters, or symbols.
- 3. If an application is accidentally submitted, contact program staff for assistance. However, applicants are still responsible for ensuring that a complete and final version of their application is properly submitted by the stated due date and time. Accidental or premature submissions do not extend the deadline or serve as a

placeholder. Applicants who mistakenly submit an incomplete or incorrect version must generate and submit a corrected application before the deadline to be considered for review. Program staff can advise on next steps, but they cannot make changes on behalf of the applicant or accept late submissions outside the system. It is strongly recommended that applicants verify their submission status and application content well in advance of the deadline.

4. An application cannot be changed after the submission due date. Some sections of the LOI – such as the Corresponding Principal Investigator, Lead Institution, Research Project Title, Research Priority, Mechanism of Support, and Keywords – will not be editable after the LOI deadline and will become part of the main application. Errata sheets or replacement files will not be accepted after the application deadline. If an application has been submitted and the applicant wishes to change the submitted application before the deadline, the Applicant must contact program staff so that the application can be unsubmitted. Then, the applicant can change and resubmit the application. The change and resubmission must occur before the submission deadline. Refer to the Contact Information section of this FOA for information on how to contact program staff.

#### 11.3.2. Application Submission Guidelines

Before it can be submitted, the application must contain all of the required sections identified in the <u>Application Components</u> section of this FOA. Applications must comply with the character/file size limitations specified in the online application. Appendices are not allowed.

Uploaded files should be titled by the categories listed in the Application Components section. Documents that require signatures must be printed, signed, scanned, and then uploaded in PDF format. Electronic signatures such as those generated by a certified process like Adobe sign are acceptable. Formatting guidelines for all documentation submitted with the online application are as follows:

1. Language: English

2. **Document Format:** PDF only

3. **Font Type/Size:** Arial, 11-point for the text and no less than 10-point for table figures and legends

4. Font Color: Black

5. Line Spacing: Single

6. **Page Size:** 8.5 x 11 inches

7. Margins: at least 1 inch, all directions, excluding required headers and footers

- 8. **Color and High-Resolution Images:** Images, graphs, figures, and other illustrations may be submitted as part of the online application. Applicants should include text to explain illustrations that may be difficult to interpret when printed in black and white.
- 9. **Scanning Resolution:** Images and figures must be of lowest reasonable resolution that permits clarity and readability. Unnecessarily large files will NOT be accepted, especially those that include only text. However, all application components

- (including uploaded attachments) must be clear, sharp, and easy to read when scanned or converted to PDF format.
- 10. References: Applicants should use a citation style that includes the full name of the article and that lists at least the first 3 authors. Official journal abbreviations may be used. An example is included below; however, other citation styles meeting these parameters are also acceptable as long as the journal information is stated. URLs of publications referenced in the application maybe included.
  - Smith, P.T., Doe, J., White, J.M., et al (2006). Elaborating on a novel mechanism for cancer progression. Journal of Cancer Research, 135: 45-67.
- 11. **Internet URLs:** Applicants may include URLs to reference publicly available publications cited in the application. However, applicants must not include URLs that link to external websites intended to provide additional information about the proposed research, personnel, facilities, or other elements of the application. Reviewers are not required to access or consider information provided via external links, and applicants should not assume that including URLs will enhance or expand their application beyond what is submitted in the main documents.
- 12. **Headers and Footers:** These should not be used unless they are part of a provided template. Page numbers may be included in the footer (see Page Numbering section below).
- 13. **Page Numbering:** Pages should be numbered at the bottom right corner of each page.

#### 11.3.3. Budget Forms

- 1. General Instructions: Budget documents are in Excel format and available in the online application and on the Biomedical Research Program's Grant Management Forms and Resources web page. When calculating the budget summary and narrative be sure to use whole dollars. The budget summary contains totals for each fiscal year and calculations for determining total grant costs. The budget summary must correspond to the calculations in the budget narrative. The budget contains two parts, Attachment V Budget Summary and Budget Narrative:
  - a. The **Budget Summary** provides an overview of the estimated budget for the life of the grant by category and by state fiscal year (July 1 June 30). Do not use calendar months to calculate the budget. The first fiscal year grant budget should be calculated for three months. Each year will be for 12 months (July June). The anticipated start date is July 1, 2026.
  - b. The **Budget Narrative** provides information regarding how expenses will be used to support the grant. Each budget category requested should include enough detail to justify the expense and should include all calculations for arriving at the totals.
  - c. Personnel/Fringe: The name, staff member's role on the project, percent of effort and any other specific rates or cost breakdowns to justify the total personnel and fringe expense. Be sure to account for any cost-of-living increases and include a statement in the narrative. Cost of living increases are

limited to three percent per year. Detailed calculations are required to justify the cost for each staff.

- **Subcontracting:** Preapproval of subcontracting is required prior to grant execution. A copy of the proposed or sample subcontract must be provided to the assigned contract manager.
- ii. Indirect Costs: Indirect cost rates may not exceed 15 percent of the total direct costs requested. Direct costs are all expense categories directly associated with the research project.

There will be a review period after the Awards are made to revise the Grant Budget Summary and Narrative. No modifications will be allowed once the Budget Revisions are complete, and the entire review packet is routing in our contract review system.

#### **12**. **APPLICATION REVIEW**

The Department will use a multi-step evaluation process before making award determinations for all applications submitted in response to this FOA. The Department will consider the outcome of each of these evaluation steps in making final funding recommendations to the State Surgeon General.

#### 12.1. **Administrative Review**

Application materials not received according to the date, time, and location specified in the Key Dates section of this FOA will be disqualified. Each application submitted by the deadline indicated in the Key Dates section will receive an administrative review verifying mandatory eligibility requirements and the completeness of the application. The administrative review includes a check for potential scientific of budgetary overlap with active or pending projects supported by the Department. The administrative review does not include review of the overall scientific impact.

Any application failing to meet all administrative requirements may be ruled ineligible for funding in response to this FOA and not entitled to further consideration and will not undergo peer review.

The Department reserves the right to disqualify any application that fails to meet the requirements of this FOA, or to waive minor irregularities in applications when it is determined to be in the best interest of the State of Florida. A minor irregularity is defined as a non-material deviation from the requirements of this FOA that does not provide the applicant with a competitive advantage, does not impact the cost of the proposed project, and does not compromise the fairness or integrity of the review process or the interests of the State. The Biomedical Research Program may, at its sole discretion, correct or allow the applicant to correct such irregularities during the review process, but is under no obligation to do so.

## 12.2. Peer Review

Department peer reviewers will assess the overall impact of all qualified/eligible applications. Peer review panels comprise reviewers with expertise in the substance and methodology of the proposed project. Individual reviewers will review and rate applications, including assessing cancer-relatedness, health impact, examining budget requests, and recommending the level of

support necessary to complete the work. Reviewers will be nationally prominent individuals drawn from various sectors in the life sciences including universities, government agencies, and industry. Reviewers will be located outside of Florida and will not be associated with any Florida-based public or private entity working in the life sciences. Before being granted access to proposals, every reviewer will be required to accept the terms of a Confidential Nondisclosure Agreement. Reviewers are required to disclose financial interests to the Department, and the Department determines if any disclosed financial interests are conflicts of interests. Reviewers with financial conflicts of interest are not allowed to review applications. Reviewers will receive honoraria for their participation and are expected to set a high standard for scientific excellence. The number and composition of peer review panels will be determined by the number and scientific range of applications received.

#### 12.2.1. Overall Impact Score

Similar to the NIH, peer reviewers will use a standard rating format, as follows:

- 1. **Exceptional:** Exceptionally strong with essentially no weaknesses.
- 2. **Outstanding:** Extremely strong with negligible weaknesses.
- 3. **Excellent:** Very strong with only some minor weaknesses.
- 4. **Very Good:** Strong but with numerous minor weaknesses.
- 5. **Good:** Strong but also at least one moderate weakness.
- 6. **Satisfactory:** Some strengths and some moderate weaknesses.
- 7. **Fair:** Some strengths but with at least one major weakness.
- 8. **Marginal:** A few strengths and a few major weaknesses.
- 9. **Poor:** Very few strengths and numerous major weaknesses.

Peer reviewers will rate all proposals for overall impact on the following criteria:

- 1. **Significance:** The importance of the topic being addressed.
- 2. **Investigators:** The qualifications of the key personnel contributing to the project.
- 3. **Innovation:** The potential for the project to shift current paradigms.
- 4. **Approach:** The appropriateness of the planned strategy, methodology, and analyses.
- 5. **Environment:** The suitability of institutional support, equipment, and physical resources.
- 6. **Health Impact:** The health impact on the people of Florida.

#### 12.2.2. Other Review Considerations

Individual peer reviewers will rate the relationship of the project to the advancement toward prevention, diagnosis, treatment, and/or cure of cancer. Peer reviewers will be asked the question: "Has the applicant made a compelling case for a strong cancer and/or tobacco-related disease relationship?" Peer reviewers will also identify any concerns regarding the proposed budget. Reviewer concerns regarding protection of human and/or animal subjects will be considered.

Applications that score within the top 30% during the individual review stage will progress to the peer review panel stage. Panelists will discuss a set of proposals and provide written comments and numeric scores.

#### 12.3. Programmatic Review

The Department and the BRAC will consider the peer review scores in a manner that eliminates or appropriately manages any conflicts of interest. Other programmatic interests, such as the availability of funds, and Program goals and preferences, will be used to form a funding recommendation to the State Surgeon General.

#### 12.4. Evaluation Reports

For all eligible and qualified applications, the Department will provide an evaluation summary (summary of the programmatic or peer review process) to the Principal Investigator following programmatic review. This report may include reviewer comments, scores, and other relevant feedback to help applicants understand how their proposal was assessed.

#### 13. AWARD NOTIFICATION

#### 13.1. Notification of Funding Decision

The applicant organization and the PI will receive written notification via email of the funding decisions. All awards in response to this FOA are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this FOA, all applicants acknowledge and consent to this condition.

#### 13.2. Requests for Reconsideration

All funding decisions of the State Surgeon General or designee are final.

#### 14. POST-AWARD GRANTEE REQUIREMENTS

#### 14.1. Terms and Conditions

After awards are made, each grantee must sign a contract, called the "Terms and Conditions," agreeing to certain legal requirements of the award. The Terms and Conditions are non-negotiable, and acceptance is required as part of the grant award process. The Department reserves the right to change or modify the Terms and Conditions as needed. By submitting a grant application pursuant to this FOA, all applicants acknowledge this requirement. The Terms and Conditions include the post-award schedule of deliverables.

#### 14.2. Reporting Requirements

If the applicant's proposal is funded, the Grantee must respond to Department requests for information for a period of five years after the end of the grant period, including any no cost extensions. The requested information may include but is not limited to long-term outcomes based on the funded project, including the value of additional grant awards for cancer research, a list of cancer presentations, a list of cancer publications in peer-reviewed journals, commercialization results and any invention disclosures, patent filings, and patents received.

Grantees are required to follow Department policies for reporting to the Department unanticipated problems and non-compliance involving the research.

#### 14.3. Open Innovation and Sharing of Publication Related Materials, Data, and Software

Publishing a scientific paper is a transaction whereby the author(s) receive credit and status in exchange for sharing their scientific findings. Authors have a responsibility to make available materials, databases, and software integral to their findings so that others may validate or refute the results and/or extend them in new directions. Grantees funded through the Department are encouraged to use material transfer agreements to make materials, data and databases, and software that result from this funding and which is integral to their research findings, freely and promptly available upon request for research use by other scientists. Also, grantees should provide a copy of any article published from research supported by this Program to the Department within three months of the date the article is published.

In accordance with the National Institutes of Health notice NOT-OD-08-033, Grantees shall submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication, in a manner consistent with copyright law. This applies to all publications resulting from Department funded projects/research. For more information on the NIH Open Access Policy, visit <a href="http://publicaccess.nih.gov/">http://publicaccess.nih.gov/</a>.

#### 14.4. Progress Reports

Detailed quarterly summaries assessing progress will be required for all funded projects. These summaries will include performance updates, successes, and unexpected barriers. Final progress reports will be due at the end of the project cycle or annually depending upon the agreement and will outline the impact on cancer research and patient care that the proposal has had on Floridians living with cancer.

#### 14.5 Financial Reports

Detailed annual financial reports will be required for all funded projects. These reports will state, by line item, all expenditures made as a direct result of activities conducted through the funded project during the most recent completed fiscal year.

In addition, detailed quarterly expenditure reports will be required for all funded projects. These reports will state, by line item, all expenditures made as a direct result of activities conducted through the funded project during the most recent completed quarter.

#### 15. **DEFINITIONS**

- 1. **Applicant:** The entity/organization applying for grant funds.
- 2. **Application materials:** Any documents or information to be included in the application.
- 3. Collaborator: An individual involved with the PI in the scientific development or execution of the project. These individuals typically devote a specific percent of effort to the project and are identified as key personnel. A collaborator may be employed by or affiliated with either the applicant/grantee institution or an institution participating in the project under a consortium or contractual agreement.
- 4. **Commercialization:** The process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others).

- 5. Consortium: A consortium should involve partnerships to be developed among investigators across Florida, with the award made to the lead organization. The lead organization of the consortium must perform a substantive role in conducting the planned research including providing oversight of all scientific, programmatic, financial, and administrative matters related to the grant. The collaborating organizations must have well-defined roles that contribute to the common scientifically rigorous research goals, and include sound background information, hypotheses, protocols, and promising practices that address clearly one or more areas of research interest. A letter of commitment from all collaborating organizations is required.
- 6. **Consultant:** An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring entity. Consultants may also include firms that provide paid professional advice or services.
- 7. **Co-Principal Investigator (Co-PI):** An individual who serves as a secondary PI. The Co-PI shares responsibility and accountability to Applicant officials, the Department, and the Collaborative for the proper conduct of the project.
- 8. Corresponding Principal Investigator (PI): The individual designated by the applicant organization legally responsible to direct the grant project. The PI is responsible and accountable to the applicant organization officials for the project's scientific and technical direction as well as the proper conduct of the project. There must be only one designated PI. (See the Eligibility section of this FOA for details regarding PI requirements.
- 9. **Department:** The Florida Department of Health.
- 10. **Eligible Institution:** Any Florida university or research hospital, Florida-based Veteran's Administration hospital, or established research institute in Florida.
- 11. Established Research Institute: An established research institute eligible for Program funding is a Florida-based nonprofit organization that is legally registered with the Florida Department of State, Division of Corporations, and holds current status under Chapter 617, Florida Statutes. The organization must maintain a physical location in Florida and have a stated purpose that includes scientific, biomedical, or biotechnological research and/or development.
- 12. **Feasibility:** The practical extent to which a project is capable of being successfully performed within the requested time and for the awarded money.
- 13. **Federal Executive Pay Scale, Executive Level II:** The U.S. Office of Personnel Management establishes executive pay schedules each year, normally around the first month of the calendar year. To view the current <u>Executive Senior Level</u> pay scale, visit the U.S. Office of Personnel Management website.
- 14. **Financial Contact**: The person responsible for financial reporting in connection with sponsored research projects.
- 15. **Full-time Faculty:** Full-time Faculty positions are defined as teaching, clinical, and research appointments carrying classroom teaching, laboratory teaching, clinical teaching or service, or research assignments equal to at least nine months per fiscal year or 0.75 FTE. This includes tenured, tenure-track, and non-tenure track appointments.

- 16. **Indirect Costs:** Indirect costs up to 15% may be included in direct cost categories for services, functions, or activities that are directly necessary for this grant.
- 17. Institutional Animal Care and Use Committee (IACUC): A committee that oversees the ethical care and use of animals in research, teaching, and testing activities within institutions.
- 18. **Institutional Biosafety Committee (IBC):** A committee that reviews and approves research that involves potentially hazardous biological agents.
- 19. **Institutional Review Board (IRB):** A committee that reviews research involving human subjects to determine if the research complies with laws, rules, and regulations, including but not limited to 45 CFR 46, and 21 CFR 50, 56, 312, and 812 as applicable.
- 20. **Grantee:** The institution to which a grant is awarded.
- 21. **Key Personnel:** Project key personnel include the PI, Co-PI(s), Project Director, and Mentor (in the case of directed research projects involving post-doctoral researcher). These personnel contribute to the scientific development or execution of the project in a substantive way, whether salaries are requested or not.
- 22. **Overlap, Commitment:** Commitment overlap occurs when any project staff has time commitments exceeding 100 percent. This is the case whether the grant includes salary support for the effort. While information on other support is only requested for the Corresponding Principal Investigator, no individual on the project may have combined commitments more than 100%.
- 23. Overlap, Financial: Financial overlap occurs when duplicate or equivalent budget items (e.g., equipment, salary) are requested in an application but are already funded or provided for by another source.
- 24. **Overlap, Scientific:** Scientific overlap occurs when: (1) substantially the same research is funded by two or more different funding sources, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more awards, regardless of the funding source.
- 25. **Radiation Safety Committee (RSC):** A group established within a research organization to oversee and enforce policies regarding the safe use of radioactive materials and radiation-producing equipment.
- 26. **Sponsored Research Official (SRO):** The individual responsible for facilitating and managing sponsored research at a research institution.
- 27. **Terms and Conditions:** An agreement whereby a project is carried out by the Grantee and one or more other organizations that are separate legal entities. In this arrangement, the Grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant.

#### 16. CONTACT INFORMATION

#### 16.1. Helpdesk

Direct all questions about the online application process and related issues (e.g., username and password problems) to Help.FLDOH@orau.org.

#### 16.2. Scientific and Programmatic Questions

This FOA is issued by the Florida Department of Health. The Public Health Research Unit manages the FOA and is responsible for answering all applicant questions. Applicants and persons acting on their behalf may contact the Department in writing via email as indicated below regarding programmatic issues. Applicants who attempt to contact Biomedical Research Advisory Council members regarding this FOA may have their applications disqualified.

To ensure equal access by all applicants to the questions and answers, all programmatic questions must be submitted in writing via email to <a href="research@flhealth.gov">research@flhealth.gov</a>. Answers to questions will be available on the Biomedical Research Program's <a href="Funding Opportunity Announcements">Funding Opportunity Announcements</a> web page. Answers to submitted questions will be posted in groups as they are received and published on the website, according to the schedule in the Key Dates section of this FOA.