



Biomedical Research Advisory Council

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

**Fiscal Year 2024-2025
Funding Opportunity Announcement**

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

Direct all questions about the online application process and related issues to:

Florida Department of Health
Division of Public Health Statistics and Performance Management
4052 Bald Cypress Way Bin A-15
Tallahassee, Florida 32399-1720
Office: 850-245-4585
Email: research@flhealth.gov

I. OVERVIEW

1. Introduction

This Funding Opportunity Announcement (FOA) covers the following three grant programs available for funding:

A. William B. “Bill” Bankhead 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. The Florida Legislature specified the purpose of the program is to advance progress toward cures for cancer through grants awarded through a peer-reviewed, competitive process. The program shall provide grants for cancer research to further the search for cures for cancer, by pursuing the following goals:

1. Significantly expand cancer research capacity in Florida.
2. Improve both research and treatment through greater pediatric and adult participation in clinical trials networks.
3. Reduce the impact of cancer on disproportionately impacted individuals.

B. 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 tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease, by pursuing the following goals:

1. Improve the health of Floridians by researching better prevention, diagnoses, treatments, and cures for cancer, cardiovascular disease, stroke, and pulmonary disease.
2. 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.
3. 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.
4. 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.
5. Stimulate economic activity in the state in areas related to biomedical research, such as the research and production of pharmaceuticals, biotechnology, and medical devices.

C. 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 Florida Legislature specified the purpose of the Initiative is to advance progress toward curing pediatric cancer through grants awarded through a peer-reviewed, competitive process. The Bella Initiative will provide grants for research to further the search for cures for pediatric cancer, by pursuing the following goals:

1. Significantly expand pediatric cancer research capacity in Florida.

2. Improve both research and treatment through greater pediatric enrollment in clinical trials networks.
3. Reduce the impact of pediatric cancer on disproportionately impacted individuals.

2. Research Priorities

The Biomedical Research Advisory Council (BRAC) advises the State Surgeon General as to the direction and scope of grant programs. The responsibilities of the council may include, but are not limited to:

- Providing advice on Program priorities and emphases.
- Developing criteria and standards for the award of research grants.

The priorities listed in this FOA were developed by the BRAC based on the Strategic Goals and Tactics developed in 2014. FOAs may vary in areas of focus and in the types of funding mechanisms offered, but will be based on the Strategic Goals, available at: [FINAL-BRAC-Strategic-Goals-and-Tactics.pdf \(floridahealth.gov\)](#).

To balance the number of grants awarded across Research Priorities, this year the Department will prioritize applications that address the following:

1. Reduction of mortality and morbidity as related to disproportionately impacted individuals.
2. Improve screening accuracy and detection in high-risk groups.
3. Resistance to front-line treatments in recurrent disease in the five cancers listed.
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 & 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.

All applications submitted in response to this FOA must be responsive to one of the following seven research priorities. Efforts to foster collaborations among institutions, researchers, and community practitioners should be included, when possible. Priority will be given to applications that address at least one of the following: lung cancer, breast cancer, prostate cancer, colon cancer, or melanoma.

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 above that disproportionately impacting individuals based on gender, race, ethnicity, or income.
2. **Disproportionately Impacted Communities:** Research that contributes to reductions in deaths due to the cancers listed in the priority section above resulting from disproportionately impacted individuals due to race, ethnicity, or income.

3. **Screening:** Improve screening accuracy, detection of high-risk subgroups, and/or improved implementation of a cancer screening program that results in an increase in early detection or prevention of at least one of the cancers listed above.
 4. **Obesity:** Enhance the understanding of the relationship between obesity, healthy weight, and at least one of the cancers listed above.
 5. **Treatment-Related Morbidities:** Expand upon research that improves 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, developmental).
 6. **Technology Transfer Feasibility (TTF):** The goals of the TTF grant mechanism are to stimulate 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. The TTF grant 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 grant mechanism include:
 - Preliminary animal model work necessary to advance the research toward commercial viability.
 - Developing and/or improving biomedical equipment useful in the prevention, diagnosis, and treatment of cancer. Developing and/or improving assays useful in the prevention, diagnosis, and treatment for cancer.
 - Developing new therapies and drugs for cancer.
 - Developing methods, materials, models, or simulations necessary for translating research findings into standard practices for the prevention, diagnosis, and treatment for cancer.
 - Eligible projects must satisfy the following requirements:
 - The technology/invention is protected or patentable.
 - A patent search has been completed with no identical inventions found.
 - A literature search has been completed and returned showing no identical published research.

- The technology/invention is free from prior disclosure(s) that would bar patentability.
 - The technology/invention is free from any conflicting prior rights.
 - The technology/invention is at a proof-of-concept stage.
 - The technology/invention is the subject of ongoing and proactive research by the scientist.
 - Potential products or services from the technology/invention meet or address an identifiable market need.
7. **Investigational New Drug (IND) or Investigational Device Exemption (IDE):** This funding mechanism supports the development of Investigational New Drug and Investigational Device Exemption applications to the United States Food and Drug Administration (FDA) as part of an application for marketing. The intent is to support promising new drug discovery and commercialization of new drugs.

8. **Emerging Therapeutics and Technologies**

This funding mechanism 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 treat of cancer and tobacco-relations morbidities also fall under this mechanism.

3. Mechanisms of Support

The following types of grants are available to pursue the above seven research priorities. Applications for Research Infrastructure grants that are reviewed and assigned exceptional scientific merit will be considered for preferential funding.

Bankhead-Coley/James and Esther King Research Programs		
Grant Mechanism	Maximum Amount (Including direct and indirect costs)	Maximum Duration
Discovery Science	\$600,000	36 Months
High-Risk, High-Reward Discovery Science	\$300,000	36 Months
Research Infrastructure	\$1,500,000	36 Months
Clinical Trials/Socio-behavioral Interventions	\$1,500,000	48 Months
High-Risk, High- Reward Clinical Research	\$750,000	48 Months
Bridge	\$100,000	6 months
Equipment	\$100,000	12 months
Non-typical Clinical Trials/Socio-behavioral Research	\$250,000	36 months
New Investigator Research (NIR)	\$300,000	36 months
Live Like Bella Pediatric Cancer Research Program		
Grant Mechanism	Maximum Amount (Including direct and indirect costs)	Maximum Duration
Multicenter ClinicalTrials	\$900,000	48 months
High-Risk, High-Reward Clinical Trials	\$300,000	48 months
Discovery Science	\$250,000	36 months
High-Risk, High- Reward Discovery Science	\$125,000	36 months
Bridge	\$100,000	6 months
Equipment	\$100,000	12 months
Non-Typical Clinical Trials/ Socio-behavioral Research	\$250,000	36 months
New Investigator Research (NIR)	\$300,000	36 months

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 & Esther King) 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.

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 Florida Department of Health (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 plan for providing access to the funded infrastructure.
- A scientific advisory process involving researchers from at least four universities and/or research institutions.
- A community advisory process that represents the perspective of participants in research, with focus on the perspectives of underserved and minority populations and communities that historically lack trust in research.

Applications may include support to address ethical, legal, and social 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, disproportionately impacted individuals, and quality indicators systems.

Tissue banking: The solicitation is for 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 and under-represented groups. 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.

Bioinformatics: The solicitation seeks 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.

Medical imaging: The solicitation seeks to 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 sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

Genomics: The solicitation seeks to expand existing infrastructure in the 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 sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

Disproportionately impacted individuals: In Florida there are significant differences in the morbidity and mortality of cancer depending on location, and other social determinants of

health. Projects may include but are not limited to expanding access to core resources for researchers, development of clinical guidelines and education programs to improve the quality and consistency of screening and clinical care, or the development of coordinating centers for research on diseases with significant disproportionately impacted individuals. 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 time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

Quality indicator systems: Adopting a continuous comprehensive quality indicator system is associated with improved cancer treatment outcomes. The solicitation seeks to support 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 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.

Clinical Trials or Social Behavioral Interventions Research

Clinical research means research that prospectively gathers evidence of the benefits and harms of various treatment/interventions 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.

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 peer review 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.

Multicenter Clinical Trials (LIVE LIKE BELLA GRANTS ONLY)

Funding from this grant mechanism for multicenter clinical trials is intended to support the evaluation of safety, efficacy, and effectiveness (Phase I, II, III, and IV) of repurposed, 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.

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 beneficial. Reporting on the role of equipment in research studies will be required.

New Investigator Research (NIR)

The intent of the NIR mechanism 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.

4. Highlights

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.

Applications will only be accepted through the online application system.

Applications conducting research with Department data must include a letter of support from the office which houses the data. For example, if conducting research using data from the Florida Cancer Data System, you must include a letter of support. Contact Heather Lake-Burger for a letter of support, at Heather.Lake-Burger@flhealth.gov to request a letter of support and more information regarding the Florida Cancer Data System. If you are interested in data from the Bureau of Vital Statistics contact Gary Sammet at Gary.Sammet@flhealth.gov. Additionally, you must indicate an overview of the data that will be requested from each data registry.

All researchers conducting behavioral health research involving tobacco cessation and control must include a letter of support from the Tobacco Free Florida Program (<http://www.tobaccofreeflorida.com/>). Please contact Jean "Raymond" Calixte at Jean.Calixte@flhealth.gov. **All letters of support must be submitted to the appropriate Department of Health office no later than August 15, 2024.**

Research studies that include research participant incentives in their budgets must receive approval from an accredited Institutional Review Board (IRB). If the research proposal is selected for department funding, the original IRB approval protocol and consent form must be

submitted to the Department before any incentives are distributed. Participant incentives in the form of cash, check, or gift cards, are permissible.

There is a defined question and answer timeframe as indicated in [Table 1](#). To ensure equal access by all applicants to questions and answers, all questions must be submitted in writing. Answers to questions will be published according to the schedule indicated in [Table 1](#). Questions that are received after the timeframe as indicated in [Table 1](#) will not be answered.

When research involves human participants, grantees are required to obtain and maintain approval from an IRB within 60 days of notice of award. Grantees should be prepared to start the regulatory review process at their institution immediately upon being notified of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department.

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 II. Eligibility and Application Requirements, Definitions, for more information about the Federal Executive Pay Scale.

The Grant Manual is an important reference document for grant awardees. It contains Department policies as well as the procedures necessary for compliance with those policies and is organized around a typical grant lifecycle. The Grant Manual can be found at [GrantAdministrationManualforFY18-191.pdf \(floridahealth.gov\)](#). Applicants are encouraged to check the Biomedical Research Program website (<https://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html>) regularly throughout the application, peer review, and award processes for Program announcements, addendums, and answers to programmatic questions.

All materials submitted to the Department are subject to the provisions of Article 1, Section 24, Florida Constitution and Chapter 119, F.S., Florida's public records law. These laws grant a right to inspect any public record to anyone upon request. All program materials, including applications, are public record. Refer to [II.6](#) for instructions on how to properly identify confidential/proprietary information.

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 also include the post-award schedule of deliverables.

5. Schedule of Important Dates

Table 1. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Funding Opportunity Announced	On or around July 15, 2024	Located on the Biomedical Research Program's website at: Biomedical Research Funding Opportunities
Letter of Intent Opens (REQUIRED)	By 8:00 a.m., EST July 29, 2024	Letter of Intent must be submitted in the online system located on the Biomedical Research Program's website. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
Informational Webinar	9:00 a.m., EST August 9, 2024	Program staff will conduct an informational webinar about the current FOA and answer participant questions in real time.
Written questions accepted	Questions may be submitted any time until 5:00 p.m. EST August 13, 2024	Email questions to: Research@flhealth.gov
Answers posted to written questions	By August 16, 2024	Questions and answers will be published on the Biomedical Research Program's website in two groups as they come in.
Letter of Intent due (REQUIRED)	Letter of Intent must be submitted by 5:00 p.m. EST August 29, 2024	Letter of Intent must be submitted in the online system located on the Biomedical Research Program's website. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
Main application opens	Anticipated date: September 10, 2024	Applications must be submitted in the online system located on the Biomedical Research Program's website.
Applications due	Applications must be submitted before 5:00 p.m. EST October 8, 2024	Applications must be submitted using the online system available on the Biomedical Research Program's website. Applications must be submitted before the deadline. Applications being edited will not be accepted after the deadline.

Awards announced	Anticipated date: January 24, 2025	Award letters and Terms & Conditions will be emailed to the Sponsored Research Official and the Corresponding Principal Investigator.
New Awardee Orientation Webinar	January 28, 2025	Discussion on Budget revisions and orientation, open to all Principal Investigators and Administrative staff
Grant Budget Revisions	February 5, 2025	Budget Template Form located in the PeerNet System Grant Forms Library
Institutional reviews due (if applicable)	Immediately after award notification, grantees should submit application(s) for all institutional authorizations including, but not limited to the Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB) and Radiation Safety Review. Project work may not begin until documentation of all approvals is provided. The documentation of institutional approval(s) must have the same project title and must be signed by the Review Board chairperson or organizational representative. Projects which include research participant incentives in their budgets must receive approval from an accredited Institutional Review Board (IRB). If the research proposal is selected for Department funding, the original IRB approval protocol and consent form must be submitted to the Department before any incentives are distributed. These documents will be kept in the grant management folder at the Department.	Grantees should be prepared to start the regulatory review process at their institutions immediately upon being notified of award.
Grants begin	Anticipated date: April 1, 2025	Contingent on verification of all eligibility requirements and regulatory approvals.
Proposal evaluation summaries available to applicants	Anticipated Date: On or about February 14, 2025	Individual evaluation reports will be provided to applicants. Applicants will be notified via e-mail when their evaluation report is available.

Any changes to the schedule will be posted to the Biomedical Research Program website. Applicants should monitor the website for changes and announcements.

II. ELIGIBILITY AND APPLICATION REQUIREMENTS

1. Cancer/Tobacco Relatedness

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

2. Eligibility Requirements

A. Eligibility Requirements

According to sections 215.5602(5) (a) and 381.922(3) (a), Florida Statutes, applications for biomedical research funding may be submitted from any university or established research institute in Florida.

Each application must identify a Corresponding Principal Investigator. The Corresponding Principal Investigator is the individual designated by the applicant organization legally responsible to direct the grant project. The Corresponding Principal Investigator 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 one designated Corresponding Principal Investigator. There may be multiple Principal Investigators on a project, but there must be only one Corresponding Principal Investigator.

The Corresponding Principal Investigator must work at an eligible Florida-based institution and meet that institution's criteria for serving as a principal investigator in addition to the eligibility requirements listed in this FOA. The Corresponding Principal Investigator 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.

Grant applications failing to meet the eligibility requirements will be rejected.

B. Letter of Intent (REQUIRED)

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 in [Table 1](#). 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)

- Name, address, telephone number, email address of the Project Director or Corresponding Principal Investigator
- Names of other research personnel
- Lead institution
- Collaborating institutions and collaborating research personnel if any
- Descriptive title of proposed research
- Research Priority
- Mechanism of Support
- General Audience Abstract (no more than 3,500 characters)
- Key Words

C. Guidelines for Florida Biomedical Research Advisory Council Member Participation

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

BRAC members shall not:

- Receive any form of financial compensation from a Bankhead-Coley, King, or Bella grant awards.
- Participate in any named role on a proposed from a Bankhead-Coley, King, or Bella grant projects in this Funding Opportunity.
- Advise applicants regarding the preparation of a specific Bankhead-Coley from a Bankhead-Coley, King, or Bella grant awards.
grant application.
- Answer any programmatic questions (eligibility, content of the Funding Opportunity, competition procedures, etc.).
- Violate any provision of Chapter 112, Part III, Florida Statutes

BRAC members may:

- Provide and sign letters of assurance/support or cover pages submitted as part of the application in cases where 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. For a list of BRAC members, refer to the Biomedical Research program website.

D. Duplication Applications and Overlap Limits

Eligible applicants can submit **one** application to the Bella Initiative, **one** application to the Bankhead-Coley program, and **one** application 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:

- One new application to the Bankhead-Coley program or one revised application, but not all.
- One new application to the James and Esther King program or one revised application, but not all.
- One new application to the Bella Initiative or one revised application, but not all.

Applicants can not submit more than two applications or substantively similar applications to the same grant funding program.

The Corresponding Principal Investigator may serve as Co-Principal Investigator 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.
- Submit the same project/research that is also being submitted by another investigator regardless of the grant mechanism.
- Submit duplicate projects or projects with significant scientific or financial overlap during the same competition year.

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.

3. Required Grant Application Components

A complete grant application package must contain all required items listed in [Table 2](#).

Table 2.a. Application Components The online application will prompt applicants of required fields and character limits for each section.	
Category	Comment
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.
General Project Information	Required. Identifies general project information, the applicant organization, and the Corresponding Principal Investigator.
General Audience Abstract	Required. Explains the proposed project in lay terms, including its relationship to the goals of the Department. Applicants will complete this in the General Project Information section of the application.
Scientific Abstract	Required. This is the scientific description of the project. Applicants will complete this in the General Project Information section of the application.
Health Impact	<p>Required. Applications must describe how the proposed project impacts the health of Floridians. Health impact means the ability 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, or 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.</p> <p>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.</p> <p>Applicants will complete this in the General Project Information section of the application.</p>
Cancer-Relatedness	Required. Provides a clear explanation of how the project is related to cancer. Applicants will complete this in the General Project Information section of the application.
Collaborator Information	Required. Identifies all key personnel.
Biographical Sketch	Required. Bio-sketches of key personnel must be uploaded as a single document in the format specified in the online system.
Consultants	Required (if there are consultants). Letters from all consultants confirming their roles in the project, including the rate/charge for consulting services must be uploaded as a single document.
Research/Project Plan	Required. Describe the specific aims including the significance, innovation, and approach. 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.

Table 2.b. Application Components
The online application will prompt applicants of required fields and character limits for each section.

Category	Comment
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	Required (if applicable). Describe use of recombinant DNA molecules involved in the research.
Survey Instruments	Required (if applicable). Survey Instruments must be uploaded as a single document.
Table, Image, or Graph	Optional. Upload a single document containing images, graphs, and figures. (There is no page limit on the number of images, graphs, and figures). Images, graphs, and figures cannot appear in the text of the application but must be uploaded separately in this section. Figure legends need to be included in the document.
Budget Template	Required. The budget must explain the planned spending. See appendix for template. The budget template can be downloaded within the online application system. The completed budget template form must be uploaded as a single document. When 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.
Budget Narrative	Required. The Budget Narrative must explain in detail how funds from each budget category will be spent for each year of project funding.
Letters of Support	Required (if applicable). If applying for a grant involving Department of Health data, a signed letter of support must be uploaded. 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.
Federal Agency Peer Review Summary Statement	Required. If the grant has previously been submitted to a federal funding agency, applicants must upload their Federal Agency Peer Review Summary Statement. For this FOA, "high scientific merit" is a percentile ranking of 16th or better or a score of 2 or better for federal funding streams that do not provide a percentile rank with peer review results.
Reportable Financial Interests	Required. The Corresponding Principal Investigator must disclose any financial interests that the researcher, the researcher's immediate family, or any other personnel on the project (sub-investigators and research staff) and their immediate families, have related to the research.

Applicants are 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 or proprietary information or is protected by a specific statutory exemption; it should be limited to the Research Project Plan section. The applicant must CLEARLY identify the 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 defend the claim in circuit court. The Department of Health will not provide legal representation to assert a confidentiality claim when a public record request is made.

4. Allowed and Disallowed Costs

The following information explains direct and indirect costs allowed by the Department, as well as disallowed costs.

A. Allowed Direct Costs

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

- Salaries, including up to a three percent increase per year.
- Background Screening: Level II (if required) should be included under other expense category.
- 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.
- Fringe benefits.
- Supplies.
- Equipment, including computed tomography (CT), magnetic resonance imaging (MRI), or other imaging systems, and improvements to existing systems. For the purposes of this FOA, "equipment" refers to items with a purchase price of over \$5,000.00 and with a useful life of over one year.
- Lab Services.
- Consultant costs, provided they do not exceed 10 percent of the total budget.
- Patient-care costs.
- Animal-care costs.
- Committee fees for IRB or Institutional Animal Care and Use.
- Consortium or contractual costs.
- Fees to obtain data from the Florida Cancer Registry Data System and Florida Office of Vital Statistics.
- Domestic travel (Travel will be reimbursed at no more than the state of Florida travel reimbursement rates. Current state of Florida reimbursement rates can be found in section 112.061, Florida Statutes. In order to implement appropriations in the General Appropriations Act for state travel and notwithstanding s. 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 voucher form in every quarter in which they will charge travel to their grant budgets. Travel is only approved within the United States (US). The State of Florida Voucher for Reimbursement of Travel Expenses should be used for all travel-related expenses unless the research institution's travel voucher/expenditure form has received prior approval from the Department of Financial Services (DFS). Support documentation for all travel-related expenses is needed, 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. The State of Florida Voucher for Reimbursement of Travel Expenses may be found [here](#).

[Grant Management Forms Library and Other Resources | Florida Department of Health \(floridahealth.gov\)](#).

- Research Participant Incentives in the form of 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 as needed. 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.
- Indirect costs up to 15% may be included in direct cost categories for services, functions, or activities that are directly necessary for this grant.

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 [II.7](#), Definitions, 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.

Work Must Occur in Florida:

Activities funded through this competition must occur 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 ten percent of the requested amount.

Subcontracts must be pre-approved in the Public Health Research Program Budget Template (Attachment V). 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.

B. Allowed Indirect Costs

Indirect costs (also referred to as IDC, Finance and Accounting, or administrative costs) may not exceed a total of 15% of the direct costs requested.

C. 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:

- Florida Department of Health personnel salary
- Construction, renovation, or remodeling
- International travel (including Canada)
- Vehicles
- Entertainment
- Employment subsidies

- Dues/Membership fees
- Lobbying
- Meals/Food (other than as part of travel costs)
- Malpractice insurance premiums

5. Inquiries and Contacts

A. Programmatic Questions about This Funding Opportunity

This Funding Opportunity is issued by the Florida Department of Health. The Public Health Research Unit manages the Funding Opportunity 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 Funding Opportunity Announcement 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 research@flhealth.gov. Answers to questions will be available on the Biomedical Research Program website: [Grant Management Forms Library and Other Resources | Florida Department of Health \(floridahealth.gov\)](http://www.floridahealth.gov/grant-management/forms-library-and-other-resources). Answers to submitted questions will be posted in groups as they are received and published on the website, according to the schedule in [I.5, Table 1](#).

B. Technical Questions about the Online Application

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

The Department recommends that applications be submitted early. Applications submitted past the deadline will not be considered, regardless of the reason.

6. Requirements for Protecting Intellectual Property

Submitted materials are subject to the provisions of Art. I, Sec. 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 research/project plan. The applicant must clearly identify the confidential information with [brackets].

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.

7. Definitions

Application materials: Any documents or information to be included in the LOI, the main application, or both.

Business entity: Per section 606.03(1), Florida Statutes, this means any form of corporation, partnership, association, cooperative, joint venture, business trust, or sole proprietorship that conducts business in Florida.

Collaborator: An individual involved with the Corresponding Principal Investigator 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. The collaborator may be employed by, or affiliated with, either the Grantee institution or an institution participating in the project under a consortium or contractual agreement.

Commercialization: The process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others).

Consortium: A consortium should involve partnerships to be developed among investigators across the State of 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.

Contractual Agreement: 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.

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.

Community-Based Participatory Research (CBPR): A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community (which can be self-defined, regional, or by interest) and has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate disproportionately impacted communities.

Cooperative Agreement: A support mechanism that will have substantial scientific and/or programmatic involvement. Substantial programmatic involvement means that after award, scientific or project staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed cooperative agreements will be published as policy announcements, program announcements, or requests for applications.

Corresponding Principal Investigator: The one individual designated by the applicant organization to direct the project to be supported by the grant. The Corresponding Principal

Investigator is responsible and accountable to applicant organization officials for the proper conduct of the project.

Department: Florida Department of Health.

Eligible Institution: Any university, research hospital, Florida-based Veteran's Administration, or established research institute in Florida.

Established Research Institute: An established research institute eligible for Program funding is an organization that is any Florida nonprofit covered under Chapter 617, Florida Statutes, with a physical location in Florida, whose stated purpose and powers are scientific, biomedical or biotechnological research and/or development and is legally registered with the Florida Department of State, Division of Corporations.

Feasibility: The practical extent to which a project is capable of being successfully performed within the requested time and for the awarded money.

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 Executive Level II pay scale, visit the website of the U.S. Office of Personnel Management and search for executive schedule.

Full-time Equivalent (FTE): The definition of a Full-time Equivalent must be in accordance with the institution's policy, used consistently by the institution regardless of the source of support, and may be different in terms of actual months per year or days per week at the applicant institution.

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.

Health Systems Research: Research that addresses health system and policy questions that concern system problems and have repercussions on the performance of the health system as a whole. It addresses a wide range of questions, from health financing, governance, and policy to problems with structuring, planning, management, human resources, service delivery, referral, and quality of care in the public and private sector.

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.

Institutional Base Salary: The annual compensation that the applicant institution pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to earn outside of duties to the applicant institution. Base salary may not be increased as a result of replacing institutional salary funds with grant funds.

Institutional Review Board (IRB): A committee that reviews research involving human subjects to determine if research complies with law, including but not limited to 45 CFR 46, and 21 CFR 50, 56, 312 and 812 as applicable.

Key Personnel: Project key personnel include the Corresponding Principal Investigator and all other Principal Investigators and Co-Principal Investigators, 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.

Nonpublic Institutions: Nonpublic institutions in Florida operating under Chapter 1005, Florida Statutes are eligible. For the purposes of the Biomedical Research Program, any branch campuses, centers, or other affiliates of a nonpublic institution are considered one and the same with that institution. Where the number of applications is limited, the institution and its branch campuses, centers, or other affiliates must coordinate submission(s) to comply with the limitation.

Overlap, Commitment: Commitment overlap occurs when any project staff has time commitments exceeding ten 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%.

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.

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.

Public University: A public (state) university is defined in section 1000.21, Florida Statutes, except as otherwise specifically provided in that statute; are the 12 named public, postsecondary institutions and any branch campuses, centers, or other affiliates of the institution. For purposes of the Biomedical Research Program, any branch campuses, centers, or other affiliates of a public university are considered one and the same with that university. Where the number of applications is limited, the university and any branch campuses, centers, or other affiliates must coordinate submission(s) to comply with the limitation.

III. INSTRUCTIONS – APPLICATION PREPARATION AND SUBMISSION

1. General Instructions for Application Submission

Applicants must register, prepare, and submit a letter of intent and application through the online system found on the Biomedical Research Program's website:

<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/colelyfoa.html>.

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.

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.

Peer reviewers evaluate only the materials in the application, and do not consider other sources of information.

A. Online Registration and Application Submission

The online system will be available to accept applications for this FOA on the date published in [Table 1](#).

To complete the online application process:

1. Applicants must register to access the online application and forms. Register for an online application on the Biomedical Research program website (<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/colelyfoa.html>) and 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.
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, contact program staff, and the application can be unsubmitted so that the applicant can change and resubmit the application. The change and resubmission must occur before the submission deadline.

B. General Application Guidelines

1. Applications must be in English.
2. The entire text of all documents uploaded into the online application must be single spaced in an easily readable font. Use standard 11-point type for the text, and no less than ten-point type for table figures and legends. Margins on all applicant created documents should be at least one inch (excluding required headers and footers). Do not use photo reduction for scanned items. Use black type for all text. The application must contain only materials that, when scanned or converted to PDF format, are clear, sharp, and easy to read.
3. All applications must be self-contained within specified page limits. Unless otherwise specified in this document, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are under no obligation to view the Internet sites.
4. Before it can be submitted, the application must contain all of the required sections identified in [Table 2](#). Uploaded files should be titled by the categories listed in the table.
5. Applications must comply with space limitations specified in the online application. Appendices are not allowed.

C. Budget Guidelines

1. General Instructions: Budget documents are in Excel format and available in the PeerNet application. 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 FY (July 1st – June 30th). Do not use calendar months to calculate the budget. The grant start date is *Anticipated* to begin April 1, 2025 (Fiscal Year 24-25) the first three months of the grant) The first fiscal year grant budget should be calculated for three months. Each remaining year will be for 12 months (July – June) The final budget year should be calculated for nine months.

- 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.
 - i. 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.

IV. POST APPLICATION SUBMISSION

1. 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 [Table 1](#). 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.

2. Evaluation of Applications

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

A. Administrative Review

Application materials not received according to the date, time, and location specified in [Table 1](#) will be disqualified. Each application submitted by the deadline indicated in [Table 1](#) will receive an administrative review verifying mandatory eligibility requirements and the completeness of the application. The administrative review includes a check for potential scientific or 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 Funding Opportunity and not entitled to further consideration and will not undergo peer review.

The Department reserves the right to disqualify any and all applications or to waive minor irregularities when doing so would be in the best interest of the State of Florida. A minor irregularity is defined as a variation from the specifications of this Funding Opportunity that does not give any applicant an advantage or benefit not enjoyed by other applicants, does not affect the cost of the application, nor adversely affects the interests of Florida. At its option, the Biomedical Research Program may correct minor irregularities, but is under no obligation to do so.

• 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.

- **Overall Impact Score**

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

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:

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

- **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.

B. 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.

C. Evaluation Reports

For all eligible and qualified applications, an evaluation report will be sent to the researcher on the date specified in [Table 1](#).

3. Notification of Funding Decision

The applicant organization and Corresponding Principal Investigator will receive written notification via email of the funding decisions as indicated in [Table 1](#). 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.

4. Requests for Re-Consideration

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

5. Grantee Requirements

A. 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. The Terms and Conditions include the post-award schedule of deliverables.

B. Grantee 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.

C. 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 accord 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 the Department funded projects/research. For more information on the NIH Open Access Policy, visit <http://publicaccess.nih.gov/>.

V. I APPENDIX

1. Reportable Financial Interests Sample

Florida Department of Health Financial Conflict of Interest in Research

Principal Investigator:

Grant Title:

Grant Number:

Step 1: Use the following tests to determine if the researcher and the researcher's immediate family, or any other personnel on the grant (sub-investigators and research staff) and their immediate families, have any of the following financial interests related to the research:

"Immediate Family" means spouse, domestic partner, children, and dependents.

"Financial Interest Related to the Research" means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.

- Ownership interest, stock options, or other financial interest of any value related to the research. Does not include mutual funds or companies publicly traded on a stock exchange.
- Compensation of any value related to the research.
- Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.
- Board or executive relationship in a company (such as a startup company but including publicly traded companies) related to the research, regardless of compensation.
- Any arrangement where the value of the ownership interests will be affected by the outcome of the research. For example, an arrangement has been made where the value of stock options given to the researcher by a startup company will vary depending on the outcome of the research.
- Any other interest that could be affected by the outcome of the research

If any of the following above conditions are met, provide a description of financial interests related to the research:

The grantee has no financial interests requiring disclosure

Signed _____

Dated _____

Failure to disclose financial interests related to the research, and failure to provide an updated disclosure at least at the time of the continuation request or if the financial interests of the researcher and personnel on the grant change, may result in:

- Immediate termination of the grant.
- Financial consequences, including repayment of all grant funds.
- Any other action required by state law.

2. Budget Summary and Budget Narrative Forms



Biomedical Research Program Grant Budget Summary

Institution: Principal Investigator:

Grant Number: Financial Contact:

BUDGET CATEGORY	FISCAL YEAR ONE 2024-2025 BUDGET (4/1/25-6/30/25)	FISCAL YEAR TWO 2025-2026 BUDGET (7/1/25-6/30/26)	FISCAL YEAR THREE 2026-2027 BUDGET (7/1/26-6/30/27)	FISCAL YEAR FOUR 2027-2028 BUDGET (7/1/27-6/30/28)	FISCAL YEAR FIVE 2028-2029 BUDGET (7/1/28-6/30/29)	FISCAL YEAR SIX 2029-2030 BUDGET (7/1/29-9/30/30)	TOTAL BUDGET
Personnel/ Fringe Benefits	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Consultant	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Consortium	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Contractual	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Equipment	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Supplies	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Travel	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Patient Care	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Other Expenses	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
DIRECT COST SUB-TOTAL:	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
Indirect Percentage:	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -
TOTAL:	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -

* All subcontracts must be pre-approved by the Department of Health.

APPLICANT

Signature of
Authorized Official _____

Name: _____

Title: _____

Date: _____

INSTRUCTIONS:

INSTRUCTIONS:

1. The budget must include the entire proposed project cost broken down by category and state fiscal year (July 1–June 30).
2. Complete the appropriate number of columns above as appropriate for the term of your grant award.
3. The total budget may not exceed the award amount and should be rounded to the nearest whole dollar amount.
4. Round down personnel costs. Insert additional rows in the Personnel chart as necessary. The budget category text boxes are limited to four lines
5. Cost of Living Adjustments are allowable on fiscal year two and forward, not to exceed 3%. Please note, a standard statement has been included on the Budget Narrative.
6. Contractual Costs - once awarded, the grantee will be required to obtain prior written approval and provide a copy of the draft/proposed subcontract.
7. Budget categories may not be altered, combined, or revised.
8. Modified Total Direct Cost (MTDC): Hard enter the total for each fiscal year. Formulas will calculate the indirect cost rate x the MTDC amount, not to exceed 15%. Excluded costs should be clearly identified on the Budget Narrative.
9. Indirect costs are limited to no more than 15% of the modified total direct costs. Use whole dollars rounding down.
10. Where appropriate, include details that show how the estimated cost was calculated.
11. Please contact your assigned Grant Manager for assistance.

Biomedical Research Grant Budget Narrative

FISCAL YEAR ONE 2024-2025 (3 Month Budget April - June)

Personnel/Fringe							
Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary/12 months x 3 months x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
TOTAL PERSONNEL COST:							\$ -
Consultant							\$ -
Consortium							\$ -
Contractual Services <i>(require pre-approval by DOH)</i>							\$ -
Equipment <i>(Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)</i>							\$ -
Supplies <i>(This line item may be adjusted to bring the budget to the exact award amount)</i>							\$ -
Travel <i>(Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)</i>							\$ -
Patient Care Costs <i>(Itemize estimated patient care costs)</i>							\$ -
Other Expenses <i>(Itemize all Other expense costs)</i>							\$ -
Indirect							\$ -
Enter percentage applied up to 15%							

Biomedical Research Grant Budget Narrative
FISCAL YEAR TWO 2025-2026 (12 Month Budget)

Personnel/Fringe

Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
TOTAL PERSONNEL COST:							\$ -

Note: A Cost of Living Adjustment up to 3% is allowed during this budget period.

Consultant \$ -

Consortium \$ -

Contractual Services (require pre-approval by DOH) \$ -

Equipment (Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category) \$ -

Supplies (This line item may be adjusted to bring the budget to the exact award amount) \$ -

Travel (Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night) \$ -

Patient Care Costs (Itemize estimated patient care costs) \$ -

Other Expenses (Itemize all Other expense costs) \$ -

Indirect \$ -

Enter percentage applied up to 15%

Biomedical Research Grant Budget Narrative

FISCAL YEAR THREE 2026-2027 (12 Month Budget)

Personnel/Fringe

Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -		\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -		\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -		\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -		\$ -
TOTAL PERSONNEL COST:							\$ -

Note: A Cost of Living Adjustment up to 3% is allowed during this budget period.

Consultant	\$ -
Consortium	\$ -
Contractual Services (require pre-approval by DOH)	\$ -
Equipment (Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)	\$ -
Supplies (This line item may be adjusted to bring the budget to the exact award amount)	\$ -
Travel (Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)	\$ -
Patient Care Costs (Itemize estimated patient care costs)	\$ -
Other Expenses (Itemize all Other expense costs)	\$ -
Indirect	\$ -
<i>Enter percentage applied up to 15%</i>	

Biomedical Research Grant Budget Narrative
FISCAL YEAR FOUR 2027-2028 (12 Month Budget)

Personnel/Fringe							
Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	\$ -	0.00%	\$ -	0.00%	-	-	-
	\$ -	0.00%	\$ -	0.00%	-	-	-
	\$ -	0.00%	\$ -	0.00%	-	-	-
	\$ -	0.00%	\$ -	0.00%	-	-	-
	\$ -	0.00%	\$ -	0.00%	-	-	-
TOTAL PERSONNEL COST:							\$ -

Note: A Cost of Living Adjustment up to 3% is allowed during this budget period.

Consultant	\$ -
Consortium	\$ -
Contractual Services (require pre-approval by DOH)	\$ -
Equipment (Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)	\$ -
Supplies (This line item may be adjusted to bring the budget to the exact award amount)	\$ -
Travel (Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)	\$ -
Patient Care Costs (Itemize estimated patient care costs)	\$ -
Other Expenses (Itemize all Other expense costs)	\$ -
Indirect	\$ -

Enter percentage applied up to 15%

Biomedical Research Grant Budget Narrative

FISCAL YEAR FIVE 2028-2029 (12 Month Budget)

Personnel/Fringe

Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
TOTAL PERSONNEL COST:							\$ -

Note: A Cost of Living Adjustment up to 3% is allowed during this budget period.

Consultant	\$ -
Consortium	\$ -
Contractual Services (require pre-approval by DOH)	\$ -
Equipment (Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)	\$ -
Supplies (This line item may be adjusted to bring the budget to the exact award amount)	\$ -
Travel (Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)	\$ -
Patient Care Costs (Itemize estimated patient care costs)	\$ -
Other Expenses (Itemize all Other expense costs)	\$ -
Indirect (Show Total Direct Costs x Rate % = \$Total Indirect Costs)	\$ -

Enter percentage applied up to 15%

Biomedical Research Grant Budget Narrative
FISCAL YEAR SIX 2029-2030 (3 Month Budget)

Personnel/Fringe

Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary/12 months x 3 months x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F + G)
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
	\$ -	0.00%	\$ -	0.00%	\$ -	\$ -	\$ -
TOTAL PERSONNEL COST:							\$ -

Note: A Cost of Living Adjustment up to 3% is allowed during this budget period.

Consultant \$ -

Consortium \$ -

Contractual Services *(require pre-approval by DOH)* \$ -

Equipment *(Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)* \$ -

Supplies *(This line item may be adjusted to bring the budget to the exact award amount)* \$ -

Travel *(Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)* \$ -

Patient Care Costs *(Itemize estimated patient care costs)* \$ -

Other Expenses *(Itemize all Other expense costs)* \$ -

Indirect \$ -

Enter percentage applied up to 15%