

Bankhead-Coley Cancer Research Program

Funding Opportunity Announcement

FY 2020-2021

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Funding Opportunity: FY 2020-2021

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NOTE: <u>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.</u>

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

Florida Department of Health
Public Health Research Unit
Division of Community Health Promotion
4052 Bald Cypress Way Bin A24
Tallahassee, Florida 32399-1725
Office: 850-245-4585
Email: research@flhealth.gov

I. OVERVIEW

1. Introduction

The William B. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (hereafter referred to as “the Program”) 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 disparate groups.

2. Research Priorities

The Biomedical Research Advisory Council (BRAC) advises the State Surgeon General as to the direction and scope of the Program. 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 Funding Opportunity were developed by the BRAC based on the Strategic Goals and Tactics developed in 2014. Funding opportunity announcements may vary in areas of focus and in the types of funding mechanisms offered, but will be based on the Strategic Research Goals, available at: http://www.floridahealth.gov/provider-and-partner-resources/research/FINAL-BRAC-Strategic-Goals-and-Tactics.pdf.

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 health disparities;
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. 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 Funding Opportunity 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.

2. Health Disparities: Research that contributes to reductions in deaths due to the cancers listed above resulting from health disparities 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.

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.

Grant Mechanism	Maximum Amount (including direct and indirect costs)	Maximum Duration
Discovery Science	$600,000	3 years
High-Risk, High-Reward Discovery Science	$300,000	3 years
Research Infrastructure	$1,500,000	3 years
Clinical Research	$1,500,000	5 years
High-Risk, High-Reward Clinical Research	$750,000	5 years
Bridge	$100,000	6 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 cancer at the molecular, cellular, and organismic levels, as well as the discovery and development of new drugs or therapies for cancer. Applications under this mechanism can include observational or cross-sectional studies not involving a clinical trial. Outcomes measure can be self-report, 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, health disparities, 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, health disparities 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, including but not limited to African-Americans and Hispanics in Florida. 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 timeframes 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 timeframes for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

- **Health disparities.** In Florida there are significant differences in the morbidity and mortality of cancer depending on location, race, ethnicity, and other social determinants of health. Projects may include but are not limited to expanding access to core resources for researchers at minority-serving organizations; 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 health disparities. 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.

- **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.

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 payline or a score of 2 or better for federal funding streams that do not provide a percentile rank with peer review results.

4. Highlights

- **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.**

- Applications will only be accepted through the online application system.

- Applications conducting research with Department of Health data must include a letter of support from the program 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.

- 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.

- 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 Institutional Review Board (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.

- The Program will 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.

- 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 http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html.

- Applicants are encouraged to check the Program website (http://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, Florida Statutes, 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 Funding Opportunity, 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 7, 2020	Located on the Program's website at: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/index.html
Letter of Intent Opens	After 5:00 p.m. EST July 7, 2020	Letter of Intent must be submitted in the online system located on the Program's website. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
GoToMeeting Informational Webinar	10:00 a.m. – 12:30 p.m. EST July 15, 2020	Program staff will conduct an informational webinar about the current FOA and answer participant questions in real time. Please join from your computer, tablet or smartphone: https://global.gotomeeting.com/join/398487117 or via telephone: **Conference Call #: 888-585-9008** **Conference Room: 852-642-835**
Written questions accepted	Questions may be submitted any time until 5:00 p.m. EST July 15, 2020	Email questions to: Research@flhealth.gov

Table 1. Schedule of Important Dates		
ACTIVITY	**DATES**	**IMPORTANT INFORMATION**
Answers posted to written questions	By July 22, 2020	Questions and answers will be published on the 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 July 29, 2020	Letter of Intent must be submitted in the online system located on the 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: August 12, 2020	Applications must be submitted in the online system located on the Program's website.
Applications due	Applications must be submitted before 5:00 p.m. EST September 16, 2020	Applications must be submitted using the online system available on the Program's website. Applications must be submitted before the deadline. Applications being edited will not be accepted after the deadline.
Awards announced	Anticipated date: March 1, 2021	Award letters and Terms & Conditions will be emailed to the Sponsored Research Official and the Corresponding Principal Investigator.
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	Grantees should be prepared to start the regulatory review process at their institutions immediately upon being notified of award.

Table 1. Schedule of Important Dates		
ACTIVITY	**DATES**	**IMPORTANT INFORMATION**
	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.	
Grants begin	Anticipated date: May 3, 2021	Contingent on verification of all eligibility requirements and regulatory approvals.
Proposal evaluation summaries available to applicants	Anticipated Date: May 17, 2021	Individual evaluation reports will be provided to applicants. Applicants will be notified via e-mail with their evaluation report is available.

Changes will be posted to the Program website. Applicants should monitor the website for changes and announcements.

II. ELIGIBILITY AND APPLICATION REQUIREMENTS

1. Cancer-Relatedness

All applicants must clearly demonstrate how the proposed project is relevant to cancer. 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.Eligible Applicants

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

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. The information it contains allows Department of Health staff to estimate the potential review workload and plan for the review. Applications will not be accepted if the researcher has not submitted a LOI by the deadline listed in Table 1. However, applicants who submit a LOI are not bound to submit an application, and a decision to submit a LOI and not submit an application will not impact eligibility for future funding opportunity announcements or be considered by peer reviewers in future funding applications. Researchers must submit an application under the same title that was specified in the LOI. Researchers are allowed to submit one LOI per program. 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.

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

- Name of Program (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 the Live Like Bella Pediatric Cancer Research Initiative (LLB), Bankhead-Coley Cancer Research Program (BC), and James and Esther King Biomedical Research Program (JK) grants and grant applications.

BRAC members shall not:

- Receive any form of financial compensation from a BC grant award.
- Participate in any named role on a proposed BC grant project in this Funding Opportunity.
- Advise applicants regarding the preparation of a specific BC 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 program website.

D.Duplicate Applications and Overlap Limits

Eligible applicants can submit **one** application to the LLB Initiative, **one** application to the BC program, and **one** application to the JK program. Applications must be different. Applicants may not submit the same applications, or substantially similar applications as determined by the Department, to the LLB, BC and JK programs.

Applicants who submitted but were not funded in the FY 2018-2019 funding competition, may submit a revised application only one time. Applicants may submit either a new application or revised application from the FY 2018-2019 funding competition but cannot submit both.

Applicants can submit:

- One new application to the BC program or one revised application, but not both
- One new application to the JK program or one revised application, but not both
- One new application to the LLB program or one revised application, but not both

Applicants cannot submit:

- Two applications to BC
- Two applications to JK
- Two applications to LLB
- The same or substantively similar application to LLB, BC, and JK

The Corresponding Principal Investigator may:

- Serve as co-PI or other role on other applications, provided they are not over-committed.

The Corresponding Principal Investigator shall not:

- Submit an application for the same research project for which he or she was previously funded as a LLB, BC, or JK grant recipient. The aims and experiments in the new proposal must be significantly different from any previously funded grants.
- Submit the same project/research to the BC program that is also being submitted by another investigator regardless of the grant mechanism.
- Submit duplicate projects or projects with significant scientific or financial overlap to the LLB, BC and JK programs 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 percent is prohibited.

3. Required Grant Application Components

A complete Grant application package must contain all required items listed in Table 2.

Table 2. Application Components

The online application will prompt applicants of required fields and character limits for each section.

Category	Comment
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	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. Consider possible long-range effects of applying knowledge gained in the research or the ability of the research to support future research grant applications or publications or patents. Applicants will complete this in the General Project Information section of the application.
Cancer-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.

Table 2. Application Components The online application will prompt applicants of required fields and character limits for each section.	
Category	**Comment**
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 IRB approval or is deemed exempt, the applicant must address all human subjects questions in the online application. If all questions are not answered, the application will be disqualified.
Vertebrate Animals	Required (if applicable). Describe protections for animals involved in the research. If vertebrate animals will be used **at any time** in the research, the applicant must address all vertebrate animals questions in the online application. If all questions are not answered, the application will be disqualified.
Recombinant DNA Molecules	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 from the program office which houses the data 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.

Table 2. Application Components The online application will prompt applicants of required fields and character limits for each section.	
Category	**Comment**
Federal Agency Peer Review Summary Statement	Required (if a). 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 3 percent increase per year.
- 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 course description or class schedule 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 $1,000.00 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
- IRB or IACUC fees

- 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 $150 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 U.S. 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 $150/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.
- Research Participant Incentives including promotional items (such as t-shirts, hats, water bottles), food and food coupons, and payment for travel expenses. Any incentive for food, food coupons, or travel expenses may not exceed the limitations in 112.061 F.S. DFS does not allow cash or check payments as research participant incentives. Gift cards can be given, however redacted monitoring logs must be submitted along with the quarterly invoice and expenditure report. CPIs should not purchase gift cards in bulk as tracking and inventory control can be difficult. Gift cards should be purchased as needed. Participant incentives must not exceed $36 per participant per visit. 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.

Administrative costs *may* be included in direct cost categories, but only under two conditions:

- the services, functions, or activities are directly necessary for this grant
- these administrative costs have not been included in the calculation of the indirect costs

The Program does not prohibit administrative costs as part of direct costs, but to be allowable, they must meet both of the above conditions. All direct costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified. Pay particular attention to these criteria with costs such as copying charges, telephone and Internet charges, maintenance contracts, etc.

Maximum Annual Base Salary Calculations:

The Program will 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 (F&A) 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, cooperative agreements, and contracts.

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 10 percent of the requested amount.

Sub-contracts must be approved in the Public Health Research Program Budget Template (Attachment V.a.). Further, the purpose of the sub-contract must be explained in the Budget Narrative (Attachement V.b.). If the sub-contract vendor is the only vendor who offers the service, please indicate. This applies to both in-state and out-of-state sub-contracts.

B.Allowed Indirect Costs

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 15 percent of the direct costs requested. Indirect costs are those costs that are incurred for the joint or common benefit of several separate organizational or financial components (cost centers) of an organization, which specifically or readily cannot be identified to a particular cost center, project, or program. Indirect cost may be charged by the lead institution, and any collaborating institutions so long as the total indirect cost charged does not exceed 15 percent of the total direct cost.

C.Disallowed Costs

All direct costs must be specifically and directly related 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 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 Program website. 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 Letter of Intent, 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). As used by the Program, commercialization includes both government and non-government markets.

Consortium or 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. These agreements typically involve a specific percent of effort from the consortium's Corresponding Principal Investigator and a breakdown of costs by category, such as personnel, supplies, and other allowable expenses, including indirect costs.

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 health disparities.

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.

Development: The systematic application of knowledge toward the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements.

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 at http://www.opm.gov/oca/ 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 systems 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.

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-PIs, 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 or not salaries are requested.

Nonpublic Institutions: Nonpublic institutions in Florida operating under Chapter 1005, Florida Statutes are eligible. For the purposes of the 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) in order to comply with the limitation.

Overlap, Commitment: Commitment overlap occurs when any project staff has time commitments exceeding 100 percent. This is the case whether or not 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 in excess of 100 percent.

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 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) in order to comply with the limitation.

III. INSTRUCTIONS FOR 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 Program's website: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/coleyfoa.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 Funding Opportunity 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 program website (http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/coleyfoa.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 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 10-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.

IV.AFTER 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, 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 of budgetary overlap with active or pending projects supported by the Department. The administrative review does not include review of the overall scientific impact.

Any application failing to meet all administrative requirements may be ruled ineligible for funding in response to this 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 Program may correct minor irregularities, but is under no obligation to do so.

B.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 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.

C.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.

D.Evaluation Reports

For all eligible and qualitied 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 in Table 1. 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.

4. Requests for Re-Consideration

All funding decisions of the State Surgeon General 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 (5) 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. APPENDIX I

1. Reportable Financial Interests

**Sample. Subject to revisions.

Florida Department of Health Financial Conflict of Interest in Research	
Corresponding Principal Investigator:	
Title of project:	
Grant number:	GRANT NUMBERS ARE ASSIGNED DURING THE POST-AWARD PROCESS. THERE IS NO NEED TO FILL THIS LINE OF THE FORM DURING THE APPLICATION STAGE.

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 Template Form

Grant Budget

The budget must include the entire proposed project cost broken down by category and fiscal year. The total budget may not exceed the award amount. Please note the table below is an embedded Excel worksheet. Double click to activate spreadsheet.

	FISCAL YEAR 2019-2020 BUDGET	FISCAL YEAR 2020-2021 BUDGET	FISCAL YEAR 2021-2022 BUDGET	TOTAL BUDGET
BUDGET CATEGORY				
Personnel / Fringe Benefits	$ -	$ -	$ -	$ -
Consultant Cost	$ -	$ -	$ -	$ -
Consortium / Contractual Cost	$ -	$ -	$ -	$ -
Equipment	$ -	$ -	$ -	$ -
Supplies	$ -	$ -	$ -	$ -
Travel	$ -	$ -	$ -	$ -
Patient Care Costs	$ -	$ -	$ -	$ -
Other $ DIRECT COST	-	$ -	$ -	$ -
SUB-TOTAL:	**$ -**	**$ -**	**$ -**	**$ -**
Indirect	$ -	$ -	$ -	$ -
TOTAL:	**$ -**	**$ -**	**$ -**	**$ -**

GRANTEE
Signature of Authorized Official:

Name:

Title:

Date:

FLORIDA DEPARTMENT OF HEALTH
Signature of Authorized Official:

Name: Bonnie Gaughan-Bailey, MPA, ASQ-CQIA

Title: Administrator, Biomedical Research Section

Date:

**Sample. Subject to revisions.

3. Budget Narrative by Year

The budget narrative must provide a cost breakdown for each budget category by fiscal year for the entire grant period. The numbers in the budget narrative should coincide with the total budget by year and category as shown in Attachment Va. Please justify expenditures in each category as it relates to the project. Where appropriate, include details that show how the estimated cost was calculated. Use additional sheets as necessary.

Name	Role on Project	Type of Appt. (months)	% Effort on Project	Annual Base Salary	Fringe	Project Salary (% effort x base salary)	Project Fringe (% effort x fringe)	Total
			0.00%	$0.00	$0.00	$0.00	$0.00	$0.00
			0.00%	$0.00	$0.00	$0.00	$0.00	$0.00
			0.00%	$0.00	$0.00	$0.00	$0.00	$0.00
			0.00%	$0.00	$0.00	$0.00	$0.00	$0.00
			0.00%	$0.00	$0.00	$0.00	$0.00	$0.00
			0.00%	$0.00	$0.00	$0.00	$0.00	$0.00
							TOTAL PERSONNEL COST:	$0.00
Insert rows as needed								

Personnel/Fringe:

Consultant Cost:

Consortium /Contractual:

Equipment:

Supplies:

Travel:

Patient Care Cost:

Other Expenses:

**Sample. Subject to revisions.

4. Terms and Conditions Template

Sample. Subject to revisions

Florida Department of Health
James and Esther King Biomedical Research Program
Bankhead-Coley Cancer Research Program
Live Like Bella Pediatric Cancer Research Initiative

Terms and Conditions

The Florida Department of Health ("Department") requires that a Grant recipient ("Grantee") for the James & Esther King Biomedical Research Program and/or the Bankhead-Coley Cancer Research Program agree to certain legally enforceable terms and conditions. "Grantee" refers to both the eligible institution and its authorized agents.

The Funding Opportunity Announcement ("FOA"), including any FOA addendums, and the application submitted by the Grantee in response thereto ("application"), are hereby incorporated by reference as part of this agreement:

- James & Esther King Biomedical Research Program Funding Opportunity Announcement: Fiscal Year 2019-2020.
- Bankhead-Coley Cancer Research Program Funding Opportunity Announcement: Fiscal Year 2019-2020.
- Live Like Bella Pediatric Cancer Research Initiative: Fiscal Year 2019-2020.

Grantee must comply with the provisions outlined in those documents, all applicable federal and State of Florida laws, rules, and regulations, and with the following terms and conditions to receive and maintain grant awards.

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1. **Grant Period and Award:** The Grant titled, (GRANT TITLE), total award amount, a description of the project funded by this grant, and other specific information about this grant are shown in Attachment I. The grant period will include the original term of the grant and all approved extensions. In the case of multi-year grants, annual continuation is not automatic and continuation requests must be submitted according to the schedule in Attachment II. The Department may grant an extension of the grant period without additional funds (no-cost extension) at the sole discretion of the Department. Awards, continuations, extensions, renewals, and payments will be made contingent upon satisfactory project performance and compliance with the grant terms and conditions. The total grant period, including extensions, may not exceed 5.5 years. The Department's performance and obligation to pay under this grant agreement are contingent upon annual appropriation by the Legislature, and/or the availability of funds.

2. **Starting the Grant Project:** This Grant may begin only with an approved budget, an approved conflict of interest, management plan, when appropriate, Institutional Review Board (IRB) approvals, and Institutional Animal Care and Use Committee (IACUC) approvals.

a. 30 Day Updates: Grantee must update the Department, in writing, every 30 days after the start date of the grant period regarding the status of all applicable regulatory approvals. Failure to keep the Department informed will result in either a financial consequences of a reduction of ten percent per invoice, or grant termination. Once applicable regulatory approvals are received the Grantee will no longer need to provide the 30 day update.

b. 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 http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html.

c. Starting the Project: If the project has not started 90 days after the start date of the Grant period, the Department will impose either a financial consequences of a ten percent reduction per invoice, or grant termination.

d. IRB and IACUC Approval: If the research requires human or animal participants the Grantee must submit application(s) for all institutional authorizations included, but not limited to the IACUC and IRB and Radiation Safety Review. The Grantee may request in writing to the Grant Manager authority to begin a portion of the project pending regulatory approvals.

3. Scope of Work and Project Adjustments:

a. The Grantee must complete the work as described in the application.

b. Any changes or adjustments in the designs, aims, or research plans as proposed in the application; any changes requiring IRB and/or IACUC approval; and any change that may result in a conflict of interest, must be submitted in writing and are subject to Department approval prior to the change taking place. Failure to obtain prior written approval from the Department of Health will result in financial consequences of ten percent per invoice.

4. Required Documentation: The Grantee will provide reports to the Department describing the impact of the research on health outcomes; scientific impact such as publications in peer review journals, presentations, patents; and any subsequent additional grant funding related to the subject research. Failure to comply with all deliverables required will result in either a financial consequences of a ten percent reduction per invoice, or grant termination.

a. Grantee must prepare and submit to the Department within 30 days of the end of each quarter; financial status reports, narrative progress reports that include a description of the impact of the research on health outcomes, and the deliverables as outlined in Attachment II. Reports must be prepared in the format specified by the Department.

b. The Grantee will make all reasonable efforts to assist the Department in gathering data required for reporting to the Legislature and Governor pursuant to sections 215.5602(10) and 381.922(4), Florida Statutes, and other laws, as applicable, both during and after the grant period. Upon request, Grantee will report a description of all outcomes resulting from this grant, including but not limited to a description of the impact of the research on health outcomes, publications, presentations, published reports, databases, additional grants and monies received, patents, invention disclosures, and copyrights, to the Department.

5. Financial Consequences: Failure to provide all documentation required will result in either a financial consequence of a reduction of ten percent per invoice, and/or grant termination.

6. **Quarter:** There are four quarters in a fiscal year, consisting of three months each. The quarters are as follows: Quarter 1 is July through September; Quarter 2 is October through December; Quarter 3 is January through March; Quarter 4 is April through June.

7. **Payment:** This Grant has a fixed payment schedule as shown in Attachment II. Payments will be contingent on Grantee compliance with these Terms and Conditions and all other grant requirements.

   a. Total per annum payments to the Grantee must not exceed the total per annum allocation as shown in Attachment I, and cannot exceed the total award amount.

   b. Grantee must request payment using the Department's invoice form. Expenses will be reviewed for allow-ability.

   c. The Grantee will only be paid for satisfactory and timely deliverables. Payment of the final invoice for this grant will take place after the end of the Grant period once all required documentation and deliverables have been received and approved.

8. **Key Personnel Requirements and Adjustments:** Project key personnel include the Principal Investigator, Project Director, Mentor, and other project personnel noted as such in the grant application.

   a. Commitment of any individual's effort greater than 100 percent is not permitted.

   b. The Grantee must establish a system to track work effort commitments of all key personnel. Effort certification documentation shall indicate the committed/actual work effort expended on the grant during the Grant period as well as percent effort for all other duties/tasks/projects. All effort assigned to this Grant must be for work directly related to the project.

   c. Prior Department approval is required for Project Director, Corresponding Principal Investigator, and Mentor changes.

   d. Reductions in Project Director or Corresponding Principal Investigator effort are not allowed within the first year and may not be decreased more than ten percent within any one year of the grant period. The amount of effort of the Project Director and/or Corresponding Principal Investigator must remain above the minimum percent required in the Funding Opportunity Announcement.

9. **Budget Adjustments:** The approved Budget Form is the annual budget approved by the Department at the beginning of the grant period and annually thereafter and includes any approved budget adjustments.

   a. The Department will reimburse the Grantee for allowable, reasonable, and necessary costs as detailed in the line item budget.

   b. The Department must review and approve any deviation from the approved budget. Any overspending in the personnel, equipment, or travel budget categories must be justified to and pre-approved by the Department. Any revisions to the Budget Form in excess of ten percent of the total amount of any one budget category being revised must be submitted to the Grant Manager on the Budget Revision Form reflecting the changes and justification. Revisions will become effective upon approval by the Department and signature by the Grantee and Department.

   c. The Department reserves the right to: 1) require further justification, 2) reject any disallowed costs, and 3) request new/revised budgets as it deems necessary.

10. **No-Cost Extensions:** Extension of a grant period without additional funds.

a. All no-cost extension requests must be received in writing in the form provided by the Department no less than 3 months prior to the ending date of the grant or date defined in Attachment II.

b. No-cost extension request are subject to review and approval or disapproval from the Department.

c. The Grant will not be eligible for more than one 6 month no-cost extension.

11. Property/Equipment: Property and equipment is defined as non-expendable, tangible property having a useful life of more than one year. All property and equipment purchased with grant funds must be (1) necessary to carry out the proposed research; (2) justified to and pre-approved by the Department; (3) inventoried and tracked throughout the grant period; and (4) protected with sufficient insurance and security safeguards.

a. All approved property and equipment must be purchased and received prior to the last 90 days of the grant period, unless prior written approval from the Department has been obtained.

b. All equipment purchased with grant funds is the property of the eligible institution, and is subject to Chapter 273, Florida Statutes, dealing with state-owned tangible personal property and the disposition thereof.

12. Fiscal Accountability: The Grantee must establish and maintain books, records, and documents (including electronic storage media) in accordance with generally accepted accounting procedures and practices, which sufficiently and properly reflect all revenues and expenditures of funds provided by the Department.

a. The Grantee must not commingle grant funds with other personal or business accounts. The Grantee must not use grant funds to supplant or replace funds from other resources.

b. The Grantee must maintain and electronically submit to the Department on a quarterly basis, sufficient documentation of all grant expenditures as proof that such expenditures are allowable, reasonable, and necessary for the work performed under this agreement. The Grantee will not charge the Department for the value of donated goods, services, or facilities; however, donations may be used to meet any required match.

c. The Grantee must develop and use a system for tracking all project costs incurred. All expenses paid with grant funds must be directly related to the project. Any grant funds utilized for purposes outside of the budget will be considered an overpayment and must be returned to the Department.

d. The Department will not be responsible for any project costs incurred before or after the grant period. Only project costs incurred during the grant period are eligible for payment. All project costs are subject to Department audit, and only those required for this project during the grant period will be allowed.

e. Per Section 112.061, Florida Statutes, reimbursement for allowed travel must be at or below the current State of Florida travel rates.

13. Matching Funds: If matching funds are a condition of this grant per the Funding Opportunity Announcement, the Grantee agrees it will specifically provide at a minimum the funds or other consideration as outlined in the application. Grantees may match more than the minimum required amount. If the Grantee does not contribute the agreed-to match amount, the total award amount may, at the discretion of the Department, be reduced proportionately to maintain the required matching ratio.

14. Return of Funds: This grant is a fixed payment grant, which provides a specific level of quarterly support without regard to actual costs incurred. The final invoice is based on a reconciliation of all costs associated with the project not to exceed the fixed amount indicated in Attachment II. The Grantee must return to the Department any overpayment of grant funds related to disallowed expenditures, funds unaccounted for due to

non-submission of required deliverables, or other unused grant funds at the end of the grant period. If the Grantee or its independent auditor identifies that overpayment has been made; the Grantee must repay the overpayment within 90 calendar days of grant end date. In the event that the Department first discovers an overpayment has been made, the Department will notify the Grantee of such a finding. Should repayment not be made in a timely manner, the Department may withhold the amount of the overpayment from any future payments under this or any other agreement. This provision will not be a limitation on any remedies at law or equity available to the Department.

15. **Monitoring:** The Grantee must permit persons duly authorized by the Department to inspect any records, papers, documents, facilities, and/or goods and services of the Grantee that are relevant to this grant, and/or interview any clients, subcontractors, and employees of the Grantee to assure the Department of satisfactory performance of the terms and conditions of this grant. Monitoring may take place at any time during the grant period or records retention period with reasonable advance notice during normal business hours. Following such evaluation, the Department may deliver to the Grantee a written report of its findings and may include written recommendations with regard to the Grantee's performance of the terms and conditions of this grant. The Grantee will correct all noted deficiencies identified by the Department within the specified period of time set forth in the recommendations. The Grantee's failure to correct noted deficiencies may, at the sole and exclusive discretion of the Department, result in any one or a combination of the following: (1) the Grantee being deemed in breach or default of this agreement; (2) the withholding of payments to the Grantee by the Department under this or any other agreement; (3) the termination of this grant.

16. **Access to Records:** All records related to this Grant or Grant Project will be subject at all reasonable times to inspection, review, or audit by federal, state, or personnel duly authorized by the Department. Persons duly authorized by the Department will have full access to and the right to examine any of the Grantee's grant and related records and documents, regardless of the form in which kept, at all reasonable times for as long as records are retained. Upon termination of the grant, and at the request of the Department, the Grantee will cooperate with the Department to facilitate the duplication and transfer of any said records or documents during the required retention period. The Department unilaterally reserves the right to terminate this grant if the Grantee refuses to allow public access to all documents, papers, letters, or other materials subject to provision of Chapter 119, Florida Statutes, made or received by the Grantee or its contractor in conjunction with this grant.

17. **Retention of Records:** The Grantee must retain all client records, financial records, supporting documents, statistical records, and any other documents (including electronic storage media) pertinent to this grant for a period of six years after the end of the grant period. If an audit has been initiated and audit findings have not been resolved at the end of the six years, the records must be retained until resolution of the audit findings or litigation, which may be based on the terms of this grant. Upon completion or termination of the grant and at the request of the Department, the Grantee will cooperate with the Department to facilitate the duplication and transfer of any said records or documents during the required retention period as specified.

18. **Financial, Scientific, Commitment Overlap and Other Support:** 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. Financial overlap is defined as accepting financial compensation from one or more other support sources for the same or substantially similar scientific aims/projects that are funded by the Department. Financial overlap is not permitted. Scientific overlap occurs when substantially the same research is funded by two or more different funding sources, or 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. Commitment overlap occurs when any project staff has time commitments exceeding 100 percent. This is the case whether or not 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 in excess of 100 percent. Other Support is defined as all financial resources, whether federal, state or private, commercial or institutional, available in direct support of an individual's research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards (not included are training awards, prizes, or gifts).

The Grantee is responsible for monitoring changes in other support for project key personnel to avoid overlap. The Grantee is responsible for notifying the Department of such changes and for resolving overlap or requesting an amendment to prevent overlap. If overlap is due to receipt of an award from another funding source during the grant period, the Grantee must immediately notify the Department and resolve the overlap by: a) modifying at least one of the awards to eliminate the overlap or b) relinquishing one of the awards. Updated information on other support may be requested by and shall be provided to the Department at any time during the grant period.

19. **Financial Conflict of Interest:** Grantee must report to the Department any interest in the list of reportable interests specified in Attachment III, regardless of any conflict of interest procedures at the Grantee's institution, at the time of the application and before the grant starts. The Grantee must have in place an administrative process to identify and resolve financial conflicts of interest that may affect the objectivity of the proposed research. The Grantee must inform the Department of any conflict of interest management plan required by the Grantee's institution prior to starting research. The Department may require an additional management plan if the plan developed by the Grantee institution is not acceptable to the Department. If a reportable interest as defined by the Department arises after the grant starts, the Grantee must immediately notify the Department within 48 hours.

20. **Assignment and Sub grants:** The Grantee will neither assign the responsibility of this grant to another party nor subcontract for any of the work contemplated under this grant without prior written approval of the Department. Any sub-license, assignment, subcontract, or transfer otherwise occurring will be null and void. No sub grants will be authorized that involve researchers outside of Florida. However, the Department may make exceptions if the service is essential and only provided outside the state, and if the sub-grant amount is less than 10 percent of the requested grant amount. The Grantee will be responsible for all work performed and all expenses incurred for this grant and for ensuring compliance with these terms and conditions. If the Department permits the Grantee to subcontract part of the work contemplated under this grant, including entering into subcontracts with vendors for services and commodities, the Department will not be liable to the subcontractor for any expenses or liabilities incurred under the subcontract and the Grantee will be solely liable to the subcontractor for all expenses and liabilities incurred under the subcontract. To the extent permitted by Florida law, the Grantee, at its expense, will defend the Department against such claims.

21. **Confidentiality:** The Grantee will maintain confidentiality of all data, files, documents, papers, electronic storage media, and records, including client records, and shall protect the privacy of human subjects related to this grant and all services provided. The Grantee must not use or disclose any information concerning human subjects under this grant for any purpose not in conformity with applicable state and federal law or regulations (including but not limited to 45 CFR 46, 160, 162, and 164, and 21 CFR 56.111 and 45) and Department Institutional Review Board policies, except upon written consent of the recipient, or his or her responsible parent or guardian, when authorized by law. Grantee must report any breach of confidentiality to the Department within 48 hours of an allegation being made.

22. **Publications, Presentations or Printing of Reports:** Any publications, presentations, printed reports, or resulting research findings related to this grant must acknowledge the appropriate funding source: Florida Department of Health, James & Esther King Biomedical Research Program, Florida Department of Health, Bankhead-Coley Cancer Research Program. Grantee shall notify the Department of all publications,

presentations, printed reports, and resulting research findings created for this project both during the grant period and for a period of six years after the grant period.

23. **Public Access:**

    a. Upon publication of their work, grantees funded through this Program are encouraged to make materials, data and databases, and software that result from this funding and which is integral to their publication, freely and expeditiously available upon request for research use by other scientists, utilizing materials transfer agreements.

    b. In concert with the National Institutes of Health (NIH) notice NOT-OD-08-033, the Grantee will 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.

24. **Patents, Copyrights, and Royalties:** Notwithstanding the provision at Section I.T of the Standard Contract, the following provisions will apply to all inventions, including intellectual property, created under this grant:

    a. All inventions will be the property of the Grantee or business partner if a written agreement has been executed; and Grantee will retain the entire right, title and interest to such.

    b. The Department will have a fully paid up, non-exclusive, non-transferable, irrevocable license to practice or have practiced or to use or have used the invention for or on behalf of the State of Florida.

    c. Grantee will disclose all inventions to the Department within two months of patent application and/or any licensing event, and will subsequently report on commercialization progress regarding patenting (filing dates and issue dates), licensing, and commercialization events.

    d. Grantee will make reasonable efforts to commercialize such invention through patenting and licensing and will make reasonable efforts to give preference to Florida-based companies.

    e. If the Grantee seeks to apply for copyright, trademark or patent when commercially reasonable for any property created, developed or invented as a result of services provided under this grant, the Grantee will furnish the Department with a description of said property and a copy of any licensing obtained.

    f. Grantee will report to the Department, upon request, any progress in securing or exploiting such inventions, trademarks, copyrights, or patents both during and after the grant period.

    g. It is expressly agreed that neither Grantee nor Department transfers by operation of this Agreement to the other party any right in or license to any patents, copyrights, or other proprietary right owned as of the commencement date of the Agreement or arising outside of the research conducted under this Agreement.

25. **Policy Regarding Scientific Misconduct:** The following provisions will apply to ensure research integrity and manage scientific misconduct.

    a. Applicants for, and recipients of, grants must promptly inform the Department of any notices of scientific misconduct or suspensions. If an administrative action for scientific misconduct is imposed by the Department of Health and Human Services (HHS), by his/her own institution, or by any other regulatory agency, the Grantee must notify the Department within 48 hours. Grantee must provide a copy of the final notice of the administrative action (i.e. after the disposition of any appeal) to the Department either at the time of application or within thirty (30) days of the imposition of the administrative action.

    b. Each eligible institution that receives or applies for a grant must certify establishment of administrative policies consistent with 42 CFR 50, Subpart A, "*Responsibilities for PHS Awardee and Applicant Institutions for Dealing with and Reporting Possible Misconduct in Science," and 42 CFR 94, "Public Health Service Standards for the Protection of Research Misconduct Whistleblowers.*"

26. Human Subjects: The following provisions will apply if the project involves human subjects:

a. Grantee must comply with all applicable federal and state laws and regulations, including 45 CFR 46, 45 CFR 160 and 164, and 21 CFR 50, 56, 312, 812, and other applicable regulations when research is covered by regulations or the organization has committed to applying federal regulations or equivalent protections to all research.

b. Grantee is responsible for safeguarding the rights and welfare of human subjects in Department-supported projects. Grantees proposing to involve human subjects in nonexempt research must provide, upon request, a copy of the organization's Assurance of Compliance with the Office of Human Research Protections (OHRP), and must establish and maintain appropriate policies and procedures for the protection of human subjects.

c. Grantees are required to obtain and maintain approval from an IRB within 60 days of notice of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department.

d. When appropriate, Grantee agrees to define the arrangements for medical care for research-related injury before the research starts and communicate it to prospective research participants. This does not require any particular party to be responsible for such care; it requires that it be made clear to participants through the informed consent document/process who will provide medical care and who will be responsible to pay for it should a participant experience a research-related injury.

e. Grantee agrees to report to the Department within 48 hours any expiration of IRB approval, serious or continuing non-compliance, unanticipated problems involving risks to participants or others, and any suspension or termination of IRB approval. The Grantee IRB agrees to report to the Department when reporting to federal officials any serious or continuing non-compliance or unanticipated problem involving risks to participants or others.

f. During the time that one or more IRB approval(s) is expired, all activities covered by the expired IRB approval(s) must stop until approval is obtained, and expenses for those activities during the expired period will be disallowed.

g. Grantee must comply with the "*NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*."

27. Vertebrate Animals: If this project involves the use of vertebrate animals, the following terms apply.

a. Grantee is responsible for the humane care and use of animals in Department-supported research activities. Grantee must abide by the Animal Welfare Act as amended (7 USC 2131-2159) and other Federal statutes and regulations relating to animals.

b. Grantee must obtain, maintain, and provide to the Department active verification or certification of Institutional Animal Care and Use Committee (IACUC) approval before project work can begin. The verification must include corresponding principal investigator name, project name, approval and expiration dates, and signature of the approving authority chairperson.

c. Grantee agrees to report within 48 hours to the Department any expiration of IACUC approval, serious or continuing non-compliance, and any suspension or termination of IACUC approval.

d. During the time that the IACUC approval is expired, all activities covered by the expired IACUC approval must discontinue until a renewal is obtained, and expenses for those activities during the expired period will be disallowed.

28. **Recombinant DNA**: All research involving recombinant DNA techniques must meet the requirements of NIH Notice NOT-OD-02-052, "*NIH Guidelines for Research Involving Recombinant DNA Molecules.*"

29. **Stem Cells:** All research involving human stem cells must meet the requirements of the "National Institutes of Health Guidelines for Human Stem Cell Research."

30. **Lobbying:** Pursuant to sections 11.062 and 216.347, Florida Statutes, no portion of grant funds will be used for lobbying.

31. **Insurance:** The Grantee must provide adequate liability insurance coverage on a comprehensive basis at all times during the grant period. Upon execution of this grant, unless it is a public college or university as identified in Chapter 1004, Florida Statutes, the Grantee accepts full responsibility for identifying and determining the type(s) and extent of liability insurance necessary to provide reasonable financial protections for the Grantee and the clients to be served under this grant, if any. Upon execution of this grant, upon request the Grantee must furnish the Department written verification supporting both the determination and existence of such insurance coverage. Such coverage may be provided by a self-insurance program established and operating under the laws of the State of Florida. The Department reserves the right to require additional insurance where appropriate. Insurance must be secured from a company licensed to do business in the State of Florida.

32. **Florida Single Audit Act Financial Audit:** The Grantee must comply with the provisions of the Florida Single Audit Act, section 215.97, Florida Statutes, as applicable. The following provisions apply:

    a. The Grantee is required to maintain separate accounting of revenues and expenditures of funds and maintain sufficient documentation of all expenditures incurred (e.g., invoices, canceled checks, payroll detail, bank statements, etc.) under this contract that evidences that expenditures are:

        i. Allowable under the contract and applicable laws, rules, and regulations;

        ii. Reasonable; and

        iii. Necessary in order for the Grantee to fulfill the obligations under these Terms and Conditions.

    b. The aforementioned documentation is subject to review by the Department and/or the State Chief Financial Officer and the Grantee will comply timely with any requests for documentation.

33. **Termination:** Regardless of the cause of termination, the Grantee must comply with the terms and conditions of this grant at all times during and after the grant period. The Grantee may be reimbursed for allowable costs incurred and any irrevocable charges through the date of termination up to the total award amount.

    a. This grant may be terminated by the Grantee upon no less than 30-calendar days notice in writing, without cause, at no additional cost.

    b. This grant may be terminated by the Department upon no less than 30-days notice, without cause, at no additional cost, unless a different notice period is mutually agreed upon by the parties or outlined elsewhere herein. The provisions herein do not limit the Department's right to any legal remedies.

    c. In the event funds to finance this grant become unavailable, the Department may terminate this grant upon no less than 24 hours notice in writing to the Grantee. The notice will be delivered by certified mail, return receipt requested, or in person with proof of delivery. The Department will be the final authority as to the availability and adequacy of funds.

    d. In the event of research non-compliance or violation of the terms of this agreement, the Department may terminate this research grant upon no less than 24 hours notice in writing to the Grantee.

34. **Indemnification:** Unless the Grantee is an agency or subdivision of the State of Florida or a public college or university as identified in Chapter 1004, Florida Statutes, the Grantee will be liable for and will indemnify, defend, and hold harmless the State of Florida, its officers, employees and agents to the full extent allowed by law from all losses, expenses, claims, damages, actions, suits and judgments, consequential or otherwise and including attorneys' fees and costs, arising out of any act, actions, neglect, or omissions by the Grantee, its agents, subcontractors, or employees during the performance or operation of this grant, whether direct or indirect, and whether to any person or tangible or intangible property. Only adjudication or judgment after highest appeal is exhausted specifically finding the Grantee not liable will excuse performance of this provision.

    Nothing in this grant agreement is intended to serve as a waiver of sovereign immunity, nor will anything in this grant agreement be construed as consent by a state agency or political subdivision of the State of Florida to be sued by third parties in any matter arising out of this grant agreement. If the Grantee is an agency or subdivision of the State of Florida, the Grantee agrees to be fully responsible for its acts of negligence, or its agents' acts of negligence when acting within the scope of their employment or agency, and agrees to be liable for any damages resulting from said negligence. Nothing herein is intended to serve as a waiver of sovereign immunity by any Grantee to whom sovereign immunity may be applicable.

35. **Dispute, Dispute Resolution, and Renegotiation:**

    a. Failure of this agreement to cite all applicable state and federal laws and regulations does not waive compliance requirements.

    b. Failure of the Department to declare any default immediately upon the occurrence thereof, or delay in taking any action in connection therewith, does not waive such default. The Department shall have the right to declare any default at any time and take such action as might be lawful or authorized hereunder, in law or in equity. No Department waiver of any term, provision, condition or covenant hereof will be deemed to imply or constitute a further Department waiver of any other term, provision, condition or covenant hereof, and no payment by the Department will be deemed a waiver of any default hereunder.

    c. Modifications of provisions of this agreement will only be valid when they have been reduced to writing and duly signed by both parties.

    d. The Department will be entitled to assign or transfer, in whole or part, its rights, duties, or obligations under this agreement to another governmental agency in the State of Florida upon giving prior written notice to the Grantee.

36. **Contact:**

    a. All correspondence relating to contractual matters should be directed to research@flhealth.gov or via mail to Florida Department of Health, Office of Public Health Research, Biomedical Research Programs, 4052 Bald Cypress Way, Bin A-24, Tallahassee, FL 32399-1749. The Department requires original signatures for all grant contract matters (invoices, budgets, and reports). These documents must be mailed to the above address.

    b. A Vendor Ombudsman has been established within the Department of Financial Services, whose duties include acting as an advocate for Grantees who may be experiencing problems in obtaining timely payment from a state agency. The Vendor Ombudsman may be contacted at (850) 413-5516 or (800) 342-2762, the State of Florida Chief Financial Officer's Hotline.

I have read the above Terms and Conditions and understand each section.

The parties hereto have caused these Terms and Conditions to be executed by their undersigned officials as duly authorized.

GRANTEE:

Signature of Authorized Official	Date
Typed or Printed Name of Authorized Official	Eligible Institution Name

FLORIDA DEPARTMENT OF HEALTH:

Signature of Authorized Official	Date
	Florida Department of Health

Attachment I

Florida Biomedical Research Programs

Terms and Conditions

Program:	
Program CSFA #:	
Grant ID:	
Type of Grant:	
Institution:	
Corresponding Principal Investigator:	
Project Title:	
General Audience Abstract:	
Grant Period:	
Total Grant Award:	
Year One Amount:	
Year Two Amount:	
Year Three Amount:	
Year Four Amount:	
Year Five Amount:	

Attachment II

Schedule of Deliverables and Payments

Florida Biomedical Research Programs **Terms and Conditions**		
Bankhead-Coley Cancer Research Program or James and Esther King Biomedical Research Program Grant Title:		
Deliverable	**Period Covered**	**Due Dates**
FISCAL YEAR 2018-2019		
• 3rd Quarter Progress Report • 3rd Quarter Financial Report • 3rd Quarter Expenditure Report • Proof of Liability Insurance • Invoice for $	Date of Execution - (insert date)	(insert date)
• 4th Quarter Progress Report • 4th Quarter Financial Report • 4th Quarter Expenditure Report • Invoice for $	(insert date)	(insert date)
FISCAL YEAR 2019-2020		
• 1st Quarter Progress Report • 1st Quarter Financial Report • 1st Quarter Expenditure Report • Invoice for $	(insert date)	(insert date)
• 2nd Quarter Progress Report • 2nd Quarter Financial Report • 2nd Quarter Expenditure Report • Invoice for $	(insert date)	(insert date)
Cumulative Grant Continuation Progress Report ***Please note this report will be peer reviewed along with the quarterly Financial and Expenditure Reports. Additionally, the Quarterly Invoice will not be processed for payment until this report is received by the Department.**	Date of Execution – (insert date)	(insert date)
• 3rd Quarter Progress Report • 3rd Quarter Financial Report • 3rd Quarter Expenditure Report • Proof of Liability Insurance • Invoice for $	(insert date)	(insert date)
• 4th Quarter Progress Report • 4th Quarter Financial Report	(insert date)	(insert date)

• 4th Quarter Expenditure Report • Invoice for $		
FISCAL YEAR 2020-2021		
• 1st Quarter Progress Report • 1st Quarter Financial Report • 1st Quarter Expenditure Report • Invoice for $	(insert date)	(insert date)
• 2nd Quarter Progress Report • 2nd Quarter Financial Report • 2nd Quarter Expenditure Report • Invoice for $	(insert date)	(insert date)
Cumulative Grant Continuation Progress Report ***Please note this report will be peer reviewed along with the quarterly Financial and Expenditure Summary Reports. Additionally, the Quarterly Invoice will not be processed for payment until this report is received by the Department.**		
• 3rd Quarter Progress Report • 3rd Quarter Financial Report • 3rd Quarter Expenditure Report • Proof of Liability Insurance • Invoice for $	(insert date)	(insert date)
• 4th Quarter Progress Report • 4th Quarter Financial Report • 4th Quarter Expenditure Report • Invoice for $	(insert date)	(insert date)
FISCAL YEAR 2021-2022		
IF REQUESTING A 6 MONTH NO-COST EXTENSION SUBMIT THE FOLLOWING: • No-Cost Extension Request Form • Cumulative Grant Progress Report	Life of the Grant	(insert date)
• 1st Quarter Progress Report • 1st Quarter Financial Report • 1st Quarter Expenditure Report • Invoice for $	(insert date)	(insert date)
• Final Cumulative Grant Progress Report • Final Financial Report	Life of the Grant	≤ 60 days after the end of grant period

• Final Expenditure Report		
• Final Invoice is based on a reconciliation of all cost associating with project not to exceed		≤ 60 days after the end of grant period

VI. APPENDIX II: SUPPORTING DOCUMENTS

OMB No. 0925-0001 and 0925-0002 (Rev. 9/17 Approved Through 03/31/2020)

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1. Biographical Sketch

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

Please refer to the Biographical Sketch instructions in the General Application Guide for NIH and Other PHS Agencies, R&R Senior/Key Person Profile Form, in order to complete sections A, B, C, and D of the Biographical Sketch.

Samples are also available here for your reference.

2. Human Subjects Form

If human subjects are involved in this project at any point at any site, answer the following questions.

Although no specific word limit applies to this section of the application, please be concise

Human Participant Protection / Institutional Review Board Approval

- ○ IRB approval has been obtained
- ○ IRB approval is pending

Describe the proposed involvement of human subjects in the work outlined in the Research/Project Plan section in the space provided below.

Describe the characteristics of the subject population, including their anticipated number, age range, gender, race, ethnicity, and health status. Identify the criteria for inclusion or exclusion of any subpopulation in the space provided below.

Explain the rationale for the involvement of special classes of subjects, such as pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable in the space provided below.

Identify the sources of research/project material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for project purposes or whether use will be made of existing specimens, records, or data. Indicate whether data about specimens will be submitted to, or held for inspection by, the Food and Drug Administration (FDA) as part of an application for marketing a drug or device in the space provided below.

Describe plans for the recruitment of subjects and the consent procedures to be followed. Include how consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. State if the Institutional Review Board (IRB) has authorized a modification or waiver of the elements of consent or the requirement for documentation of consent. The informed consent form, which must have IRB approval, should be submitted to the Program only if requested.

Describe potential risks to the subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness in the space provided below.

Where appropriate, describe alternative treatments and procedures that might be advantageous to the subjects in the space provided below.

Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness in the space provided below.

Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety and privacy of subjects in the space provided below.

Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of applicant certification to the Food and Drug Administration and its response has elapsed or has been waived and/or whether use of the test article has been withheld or restricted by the Food and Drug Administration.

Gender and Minority Inclusion for Research Involving Human Subjects

Women and members of minority groups and their subpopulations should be included in all research funded by the Department, unless there is a reason that that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Exclusion under other circumstances may be made based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion, except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This applies to research subjects of all ages. Address the inclusion of women and members of minority groups and their subpopulations in developing a research design appropriate to the scientific objectives of the study.Describe the composition of the proposed study population in terms of gender and racial/ethnic group, and provide a rationale for selection of such subjects in the space provided below.

Provide the proposed enrollment beginning and end dates. Include a description of proposed outreach programs for recruiting women and minorities as participants in the space provided below.

Provide compelling rationale and justification for requesting any exclusion noted above. When proposing Phase III clinical trials, show whether clinically important gender or race/ethnicity differences are to be expected, and how the trial is designed to accommodate any differences.

3. Recombinant DNA Molecules Form

Describe use of recombinant DNA molecules in the research

Describe the rationale and procedures for use of recombinant DNA molecules in the research.

4. Stem Cell Research Form

If the proposed project involves stem cells at any time during the project, answer the questions below.

Type of Stem Cell

If activities involving stem cells, whether or not exempt from Federal regulations for the protection of human subjects, are planned at any time during the proposed project period, either at the applicant organization or at any other site or collaborating organization, check the type of stem cell.

- ☐ Adult
- ☐ Embryonic
- ☐ Animal

If the project involves stem cells, please identify the source(s) of stem cells being used and include a very brief description of the relevant research activity. If the cell line(s) proposed to be used are not from the NIH Stem Cell Registry (Registry), provide a strong justification for why an appropriate cell line cannot be chosen from the Registry at this time.

Provide a detailed description of the proposed use of animals in the work outlined in the Research/Project Plan section or Vertebrate Animals form. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.

5. Vertebrate Animals Form

If the proposed project involves vertebrate animals at any time during the project, answer the questions below.

Although no specific word limit applies to this section of the application, please be concise

1. Provide a detailed description of the proposed use of animals in the work outlined in the Research/Project Plan section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work. Provide a description if the animals will be used at a collaborating site, or location other than the principal researcher's organization.

2. Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.

3. Provide information on the maintenance and veterinary care of the animals involved.

4. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research.

Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

5. Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association. If not, present a justification for not following the recommendations.

6. Institutional Animal Care and Use Committee Approval

- ○ IACUC approval has been granted within the previous three years.
- ○ IACUC approval is pending.