



**Bankhead-Coley Cancer  
Biomedical Research Program**

**James and Esther King  
Biomedical Research Program**

**Live Like Bella Pediatric Cancer  
Biomedical Research Program**

**Fiscal Year 2023-2024**

**Funding Opportunity Announcement**  
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**Funding Opportunity: FY 2023-2024**

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

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

Florida Department of Health  
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](mailto:research@flhealth.gov)

# I. OVERVIEW

## 1. Introduction

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

### A. William B. “Bill” Bankhead and David Coley Cancer Research Program

The William B. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (Bankhead Coley) is established in section 381.922, Florida Statutes. The Florida Legislature specified the purpose of the program is to advance progress toward cures for cancer through grants awarded through a peer-reviewed, competitive process. The program shall provide grants for cancer research to further the search for cures for cancer, by pursuing the following goals:

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

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

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

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

## **C. Live Like Bella Pediatric Cancer Pediatric Cancer Research Institute**

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

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

## **2. Research Priorities**

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

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

The priorities listed in this 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 disproportionately impacted individuals.
2. Improve screening accuracy and detection in high-risk groups.
3. Resistance to front-line treatments in recurrent disease in the five cancers listed.
4. Research focused on sarcomas, or leukemia and other blood cancers.
5. Prevention and treatment research evaluating programs for tobacco use reduction and prevention (James & Esther King)
6. Prevention of the transition from electronic nicotine to combustible tobacco usage or demonstrates the effectiveness of the use of electronic nicotine in the reduction or elimination of the use of combustible tobacco. Priority applications include studies on basic biology of electronic cigarettes (James and Esther King)
7. Examine the relationship between obesity and cancer, cancer treatment responsiveness, and cancer treatment-related morbidities. Applications related to other areas described in the Funding Opportunity Announcement (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, and melanoma.

- (1) **Prevention and Treatment:** Research with a focus on prevention and improved treatment or care delivery that contributes to a reduction in deaths in at least one of the cancers listed above that disproportionately impacting individuals based on gender, race, ethnicity or income.
- (2) **Disproportionately Impacted Communities:** Research that contributes to reductions in deaths due to the cancers listed in the priority section above resulting from disproportionately impacted individuals due to race, ethnicity, or income.
- (3) **Screening:** Improve screening accuracy, detection of high-risk subgroups, and/or improved implementation of a cancer screening program that results in an increase in early detection or prevention of at least one of the cancers listed above.
- (4) **Obesity:** Enhance the understanding of the relationship between obesity, healthy weight, and at least one of the cancers listed above.
- (5) **Treatment-Related Morbidities:** Expand upon research that improves scientific understanding of causes and subsequent impact of cancer/cancer-treatment related morbidities in other systems (e.g., cardiovascular, pulmonary, endocrine, lymphatic, central nervous system, reproductive, developmental).
- (6) **Technology Transfer Feasibility (TTF):** The goals of the TTF grant mechanism are to stimulate technology transfer activities for promising research discoveries that could lead to innovations in the prevention, diagnosis, treatment, and/or cure of cancer and strengthen a project's economic feasibility and commercialization prospects. The primary objective is to assist investigators in moving promising research findings toward commercialization. The TTF grant offers early-stage funding to develop intellectual property and improve its commercial potential and competitiveness for further development activities, including company formation or partnering with private interests. Projects should be designed to establish the technical/scientific merit and feasibility needed to attract commercial interest. There is no requirement for the participation of a small business partner.

Example projects appropriate for the TTF grant mechanism include:

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

Eligible projects must satisfy the following requirements:

- The technology/invention is protected or patentable.
  - A patent search has been completed with no identical inventions found.
  - A literature search has been completed and returned showing no identical published research.
  - The technology/invention is free from prior disclosure(s) that would bar patentability.
  - The technology/invention is free from any conflicting prior rights.
  - The technology/invention is at a proof-of-concept stage.
  - The technology/invention is the subject of ongoing and proactive research by the scientist.
  - Potential products or services from the technology/invention meet or address an identifiable market need.
2. 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.

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

## **Discovery Science**

Discovery science means fundamental theoretical or experimental investigative research to advance knowledge without a specifically envisaged or immediately practical application. Directed to understanding the events related to the development or prevention of tobacco-related diseases (James & Esther King) and cancer at the molecular, cellular, and organismic levels, as well as the discovery and development of new drugs or therapies. This section includes studies on basic biology of e-cigarettes.

Applications under this mechanism can include observational or cross-sectional studies not involving a clinical trial. Outcome measures can be self-reported, observational, behavioral, biologic, or genetic.

## **Research Infrastructure**

Eligible organizations may submit an infrastructure application in at least **one** of the following six areas: tissue banking, bioinformatics, genomics, diagnostic imaging, disproportionately impacted individuals, or quality indicator systems, as described on the following pages. The Florida Department of Health (Department) is particularly interested in research involving quality indicator systems, when this is linked with other priorities, such as increasing the number of Florida research networks, external funding for research infrastructure and large-scale projects, including but not limited to National Cancer Institute grants. Organizations will only be permitted to be the lead on one application but may be collaborators on applications submitted by other organizations. When organizations collaborate on more than one infrastructure application, they need to describe how the projects are different and do not overlap.

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

Applications must describe:

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

Applications may include support to address ethical, legal, and social issues in the research.

The solicitation is limited to proposals that will improve infrastructure/resources in the areas of tissue banking, bioinformatics, genomics, diagnostic imaging, disproportionately impacted individuals, and quality indicators systems.

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

**Bioinformatics.** The solicitation seeks applications to expand existing infrastructure/ resources for analysis of biomedical data, including genomic and proteomic information and the study of biological systems most relevant to cancer. Projects may include improving algorithms, databases, and modeling of biological phenomena; purchase of equipment, and software; and support for the expansion of cross-disciplinary research teams. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and timeframes for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure. Projects may include but are not limited to expanding the ability to analyze very large data sets; the identification of tissue-specific biomarkers brought on by cancer; or improvements in ways of automating clinical imaging.

**Medical imaging.** The solicitation seeks to expand existing infrastructure that improves the quality, speed, and accuracy of medical imaging or develops processes that measure the effectiveness of imaging technologies. Projects may include but are not limited to improvements in screening for lung and breast cancer or research examining the correlation between the expanded use of imaging technologies and health outcomes. Projects may include improvements to software and equipment. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

**Genomics.** The solicitation seeks to expand existing infrastructure in the areas of functional genomics, genomic biomarkers, epigenetics, next-generation sequencing, miRNA and non-coding RNA, qPCR, proteomics and proteome analysis including chromatography or mass spectroscopy. Funds are intended to be used to upgrade software and equipment that will make organizations competitive for additional funding and serve as a national resource. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

**Disproportionately impacted individuals.** In Florida there are significant differences in the morbidity and mortality of cancer depending on location, and other social determinants of health. Projects may include but are not limited to expanding access to core resources for researchers, development of clinical guidelines and education programs to improve the quality and consistency of screening and clinical care, or the development of coordinating centers for research on diseases with significant disproportionately impacted individuals. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and time frames for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

**Quality indicator systems.** Adopting a continuous comprehensive quality indicator system is associated with improved cancer treatment outcomes. The solicitation seeks to support projects that create sustainable ongoing systems to collect quantitative data about: treatment outcomes and compare them with national outcomes or treatment processes and compare them with evidence-based standards, including consensus standards, or other practice standards such as emerging findings in the research literature. The expectation is that the organization will publish treatment outcomes at least annually in a prominent place on the organization's website and publish descriptions of how the organization is using the information obtained through the collection of quality indicators to improve care. The expectation is that projects will include sustainable ongoing mechanisms to improve sharing of infrastructure/resources with external researchers and research institutes in Florida. Projects should describe measurable targets and timeframes for expanding access as well as describe a process to evaluate improved outcomes related to this infrastructure.

### **Clinical Trials or Social Behavioral Interventions Research**

Clinical research means research that prospectively gathers evidence of the benefits and harms of various treatment/interventions options for cancer, directly involves a person or group of people, or uses materials from humans, such as their behavior or collecting samples of their tissue. Applications in this area can include trials of new medications, trials of novel medication combinations, social behavioral health interventions, or health care delivery comparisons. Research can also include a focus on observational studies.

### **Bridge**

The intent of this grant mechanism is to provide interim support for promising investigator-initiated research projects that have been highly rated by national panels of peer reviewers in recent federal competitions but were not funded due to budgetary constraints. In the case of this competition, no more than 18 months may pass between having received a funding decision by a federal agency and submission of an application to the Bankhead-Coley program. Allowable federal competitions include but are not limited to those conducted by the National Institutes of Health (NIH), the Department of Defense Congressionally Directed Medical Research Programs, the National Science Foundation, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the United States Food and Drug Administration.

To be eligible, applicants must have submitted a multi-year, investigator-initiated research application to a federal agency (such as an NIH R type). The applicant must have received a peer review summary statement indicating high scientific merit. For purposes of this competition,

“high scientific merit” is a percentile ranking within five percentile points of the respective federal funding stream’s pay line or a score of 2 or better for federal funding streams that do not provide a percentile rank with peer review results.

### **Multicenter Clinical Trials (LIVE LIKE BELLA GRANTS ONLY)**

Funding from this grant mechanism for multicenter clinical trials is intended to support the evaluation of safety, efficacy, and effectiveness (Phase I, II, III, and IV) of repurposed, new, and innovative drugs and other treatments for pediatric cancers. Trials may include randomized clinical trials or innovative applications of precision medicine strategies using targeted therapies. Multicenter clinical trials need to involve investigators from at least two distinct research/clinical facilities in Florida and must be implemented in two or more locations in Florida.

### **Equipment**

The solicitation is for infrastructure/resources to augment research equipment that advances the current and future cancer research capability. The expectation is that new equipment will be shared with other researchers as beneficial. Reporting on the role of equipment in research studies will be required.

### **New Investigator Research (NIR)**

The intent of the NIR mechanism is to foster development of new investigators so they may undertake independent research that is competitive for national research funding. New investigators must have been full-time faculty for no more than six years and must work under the mentorship of a senior investigator.

## **4. Highlights**

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

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

submitted to the Department before any incentives are distributed. These documents will be kept in the grant management folder at the Department. Participant incentives in the form of cash, check, or gift cards, are permissible.

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

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

Grant funds may be used to pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. The maximum annual base salary used in calculating these payments must not exceed the Executive Level II annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See II. Eligibility and Application Requirements, Definitions, for more information about the Federal Executive Pay Scale.

The Grant Manual is an important reference document for grant awardees. It contains Department policies as well as the procedures necessary for compliance with those policies and is organized around a typical grant lifecycle. The Grant Manual can be found at <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.

Applicants are encouraged to check the Biomedical Research 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
<b>Funding Opportunity Announced</b>	On or around June 23, 2023	Located on the Biomedical Research Program's website at: <a href="http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/index.html">http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/index.html</a>
<b>Letter of Intent Opens (REQUIRED)</b>	By 8:00 a.m., EST June 23, 2023	Letter of Intent must be submitted in the online system located on the Biomedical Research Program's website. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
<b>Informational Webinar</b>	9:00 a.m., EST June 29, 2023	Program staff will conduct an informational webinar about the current FOA and answer participant questions in real time.
<b>Written questions accepted</b>	Questions may be submitted any time until 5:00 p.m. EST July 3, 2023	Email questions to: <a href="mailto:Research@flhealth.gov">Research@flhealth.gov</a>
<b>Answers posted to written questions</b>	By July 7, 2023	Questions and answers will be published on the Biomedical Research Program's website in two groups as they come in.
<b>Letter of Intent due (REQUIRED)</b>	Letter of Intent must be submitted by 5:00 p.m. EST July 21, 2023	Letter of Intent must be submitted in the online system located on the Biomedical Research Program's website. Applications without a Letter of Intent by the deadline are not eligible and will not be considered.
<b>Main application opens</b>	Anticipated date: July 26, 2023	Applications must be submitted in the online system located on the Biomedical Research Program's website.
<b>Applications due</b>	Applications must be submitted before 5:00 p.m. EST August 15, 2023	Applications must be submitted using the online system available on the Biomedical Research Program's website. Applications must be submitted before the deadline.

		Applications being edited will not be accepted after the deadline.
<b>Awards announced</b>	Anticipated date: December 20, 2023	Award letters and Terms & Conditions will be emailed to the Sponsored Research Official and the Corresponding Principal Investigator.
<b>New Awardee Orientation Webinar</b>	January 3, 2024	Discussion on Budget revisions and orientation, open to all Principal Investigators and Administrative staff
<b>Grant Budget Revisions</b>	January 3-12, 2024	Budget Template Form located in the PeerNet System Grant Forms Library
<b>Institutional reviews due (if applicable)</b>	Immediately after award notification, grantees should submit application(s) for all institutional authorizations including, but not limited to the Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB) and Radiation Safety Review. Project work may not begin until documentation of all approvals is provided. The documentation of institutional approval(s) must have the same project title and must be signed by the Review Board chairperson or organizational representative. Projects which include research participant incentives in their budgets must receive approval from an accredited Institutional Review Board (IRB). If the research proposal is selected for Department funding, the original IRB approval protocol and consent form must be submitted to the Department before any incentives are distributed. These documents will be kept in the grant management folder at the Department.	Grantees should be prepared to start the regulatory review process at their institutions immediately upon being notified of award.
<b>Grants begin</b>	Anticipated date: April 1, 2024	Contingent on verification of all eligibility requirements and regulatory approvals.
<b>Proposal evaluation summaries available to applicants</b>	Anticipated Date: On or about January 5, 2024	Individual evaluation reports will be provided to applicants. Applicants will be notified via e-mail when their evaluation report is available.

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

## II. ELIGIBILITY AND APPLICATION REQUIREMENTS

### 1. Cancer-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 (REQUIRED)**

**Submission of a Letter of Intent (LOI) is required prior to submission of an application. For collaborative applications, the lead organization is required to submit the LOI.**

Applications will not be accepted if the researcher has not submitted an LOI by the deadline listed in Table 1. Researchers must apply under the same title that was specified in the LOI.

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

- Program Name (James and Esther King Biomedical Research Program, Bankhead-Coley Cancer Research Program, or Live Like Bella Pediatric Cancer Research Initiative)
- Name, address, telephone number, email address of the Project Director or Corresponding Principal Investigator
- Names of other research personnel
- Lead institution
- Collaborating institutions and collaborating research personnel if any
- Descriptive title of proposed research
- Research Priority
- Mechanism of Support
- General Audience Abstract (no more than 3,500 characters)
- Key Words

### **C. Guidelines for Florida Biomedical Research Advisory Council Member Participation**

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

BRAC members shall not:

- Receive any form of financial compensation from a 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 Biomedical Research 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 previous fiscal year funding competition, may submit a revised application only one time. Applicants may submit either a new application or revised application from the previous fiscal year funding competition but cannot submit both.

Applicants can submit:

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

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

The Corresponding Principal Investigator may serve as Co-Principal Investigator or other role on other applications, provided they are not over-committed. The Corresponding Principal Investigator shall not:

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

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

### 3. Required Grant Application Components

A complete Grant application package must contain all required items listed in [Table 1](#).

Table 1.a. Application Components	
The online application will prompt applicants of required fields and character limits for each section.	
Category	Comment
Letter of Intent	Submission of a Letter of Intent (LOI) is required prior to submission of an application. For collaborative applications, the lead organization is required to submit the LOI.
General Project Information	Required. Identifies general project information, the applicant organization, and the Corresponding Principal Investigator.
General Audience Abstract	Required. Explains the proposed project in lay terms, including its relationship to the goals of the Department. Applicants will complete this in the General Project Information section of the application.
Scientific Abstract	Required. This is the scientific description of the project. Applicants will complete this in the General Project Information section of the application.
Health Impact	<p>Required. Applications must describe how the proposed project impacts the health of Floridians. Health impact means the ability of the research to reduce morbidity and mortality from cancer. Applications must describe how the results of the research can provide information and evidence for changes in policy, or improve health service delivery and quality of care, or improve disease prevention through improvements in health literacy and changes in behavior within a certain amount of time.</p> <p>Consider possible long-range effects of applying knowledge gained in the research or the ability of the research to support future research grant applications or publications or patents.</p> <p>Applicants will complete this in the General Project Information section of the application.</p>
Cancer-Relatedness	Required. Provides a clear explanation of how the project is related to cancer. Applicants will complete this in the General Project Information section of the application.
Collaborator Information	Required. Identifies all key personnel.
Biographical Sketch	Required. Bio-sketches of key personnel must be uploaded as a single document in the format specified in the online system.
Consultants	Required (if there are consultants). Letters from all consultants confirming their roles in the project, including the rate/charge for consulting services must be uploaded as a single document.
Research/Project Plan	Required. Describe the specific aims including the significance, innovation, and approach. Provide a bibliography of any references cited and list facilities and other resources.
Human Subjects	Required (if applicable). Describe protections for human subjects involved in the research. If human subjects will be involved <b>at any time</b> in the research, even if the project protocol has already received Institutional Review Board approval or is deemed exempt, the applicant must address all human subject questions in the online application. If all questions are not answered, the application will be disqualified.

**Table 1.b. Application Components**

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

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

Applicants are discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application.

If the application contains information that the applicant believes constitutes trade secrets or proprietary information or is protected by a specific statutory exemption; it should be limited to the Research Project Plan section. The applicant must CLEARLY identify the information with [brackets] and a footnote that specifies the law that makes the document or information exempt from the public records laws. If a public records request is made involving documents with declarations of confidentiality, the Department will notify the applicant so that he/she may defend the claim in circuit court. The Department of Health will not provide legal representation to assert a confidentiality claim when a public record request is made.

## 4. Allowed and Disallowed Costs

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

### **A. Allowed Direct Costs**

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

- Salaries, including up to a three percent increase per year.
- Background Screening: Level II (if required) should be included under *Other* expense category
- Tuition: To assure that the tuition waiver or reimbursement is related to the research project, a course description or class schedule must be submitted with the quarterly invoice that includes the tuition waiver or expenditure. Tuition waivers or support should be included in the approved Public Health Research Program Budget Template and the purpose of the tuition support must be included in the final Budget Narrative. Submitting class schedule or attestation of verification by the Principal Investigator with quarterly invoices is required for payment.
- Fringe benefits
- Supplies
- Equipment, including computed tomography (CT), magnetic resonance imaging (MRI), or other imaging systems, and improvements to existing systems. For the purposes of this FOA, "equipment" refers to items with a purchase price of over \$5,000.00 and with a useful life of over one year.
- Lab Services
- Consultant costs, provided they do not exceed 10 percent of the total budget
- Patient-care costs
- Animal-care costs
- IRB or Institutional Animal Care and Use Committee 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 \$175 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 \$175/night), parking, rental car, gas, ground transportation, as well as registration, meeting agenda/schedule, and copy of any presentation(s) made. The State of Florida Voucher for Reimbursement of Travel Expenses may be found [here. Grant Management Forms Library and Other Resources | Florida Department of Health \(floridahealth.gov\)](https://www.floridahealth.gov/grant-management/forms-library-and-other-resources)

- Research Participant Incentives can be given in the form of cash, check, or gift card. Gift cards should not be purchased in bulk as tracking and inventory control can be difficult. Gift cards should be purchased as needed. If awarded, the original approved IRB protocol and consent form must be submitted to the Department before any participant incentive charges may be made to the grant. Each grant agreement executed will reference the approved IRB protocol in the method of payment section of each grant agreement.
- Indirect costs up to 15 percent *may* be included in direct cost categories for services, functions, or activities that are directly necessary for this grant.

### **Maximum Annual Base Salary Calculations:**

Grant funds may be used to pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. The maximum annual base salary used in calculating these payments must not exceed the Executive Level II annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See [II.7](#), Definitions, for more information about the Federal Executive Pay Scale. This salary cap excludes fringe benefits, facilities, and administrative (Finance & Accounting) expenses, and any income that an individual may be permitted to earn outside of the duties to the applicant organization. This provision is consistent with the NIH salary limitations on grants and cooperative agreements.

### **Work Must Occur in Florida:**

Activities funded through this competition must occur in Florida. All work (effort) must occur, and funds must be spent in Florida at the applicant organization and any collaborating entities. However, the Department may make exceptions if the service is essential and only provided outside Florida, and if the amount is less than 10 percent of the requested amount.

Subcontracts must be pre-approved in the Public Health Research Program Budget Template (Attachment V). The Budget Narrative must justify the purpose of the subcontract, whether this is the only vendor that can perform the services, regardless if they are in-state or out-of-state.

### **B. Allowed Indirect Costs**

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

### **C. Disallowed Costs**

All direct costs must be specifically and directly related and allocated to the project, necessary for the project's completion, adequately justified, and made during the active grant period. Any other costs are disallowed. Additionally, the following items shall NOT be paid for with grant funds:

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

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

## **5. Inquiries and Contacts**

### **A. Programmatic Questions about This Funding Opportunity**

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

To ensure equal access by all applicants to the questions and answers, all programmatic questions must be submitted in writing via email to [research@flhealth.gov](mailto:research@flhealth.gov). Answers to questions will be available on the Biomedical Research Program website: [Grant Management Forms Library and Other Resources | Florida Department of Health \(floridahealth.gov\)](http://www.floridahealth.gov/grant-management/forms-library-and-other-resources). Answers to submitted questions will be posted in groups as they are received and published on the website, according to the schedule in [1.5, 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](mailto:Help.FLDOH@orau.org).

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

## **6. Requirements for Protecting Intellectual Property**

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

Applicants are strongly discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. If the application contains information that the applicant believes constitutes trade secrets, intellectual property, proprietary information, or information protected by a specific statutory exemption, it should be limited to the research/project plan. The applicant must clearly identify the confidential information with [brackets].

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

## 7. Definitions

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

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

**Collaborator:** An individual involved with the Corresponding Principal Investigator in the scientific development or execution of the project. These individuals typically devote a specific percent of effort to the project and are identified as key personnel. The collaborator may be employed by, or affiliated with, either the Grantee institution or an institution participating in the project under a consortium or contractual agreement.

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

**Consortium:** A consortium should involve partnerships to be developed among investigators across the State of Florida, with the award made to the lead organization. The lead organization of the consortium must perform a substantive role in conducting the planned research including providing oversight of all scientific, programmatic, financial, and administrative matters related to the grant. The collaborating organizations must have well-defined roles that contribute to the common scientifically rigorous research goals, and include sound background information, hypotheses, protocols, and promising practices that address clearly one or more areas of research interest. A letter of commitment from all collaborating organizations is required.

**Contractual Agreement:** An agreement whereby a project is carried out by the Grantee and one or more other organizations that are separate legal entities. In this arrangement, the Grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant.

**Consultant:** An individual hired to give professional advice or services for a fee, normally not as an employee of the hiring entity. Consultants may also include firms that provide paid professional advice or services.

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

**Cooperative Agreement:** A support mechanism that will have substantial scientific and/or programmatic involvement. Substantial programmatic involvement means that after award, scientific or project staff will assist, guide, coordinate, or participate in programmatic activities beyond the normal stewardship responsibility in the administration of grants. Proposed

cooperative agreements will be published as policy announcements, program announcements, or requests for applications.

**Corresponding Principal Investigator:** The one individual designated by the applicant organization to direct the project to be supported by the grant. The Corresponding Principal Investigator is responsible and accountable to applicant organization officials for the proper conduct of the project.

**Department:** Florida Department of Health.

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

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

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

**Federal Executive Pay Scale, Executive Level II:** The U.S. Office of Personnel Management establishes executive pay schedules each year normally around the first month of the calendar year. To view the current Executive Level II pay scale, visit the website of the U.S. Office of Personnel Management at <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2022/EX.pdf> and search for executive schedule.

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

**Full-time Faculty:** Full-time Faculty positions are defined as teaching, clinical, and research appointments carrying classroom teaching, laboratory teaching, clinical teaching or service, or research assignments equal to at least nine months per fiscal year or 0.75 FTE. This includes tenured, tenure-track, and non-tenure track appointments.

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

**Indirect Costs:** Indirect costs up to 15 percent *may* be included in direct cost categories for services, functions, or activities that are directly necessary for this grant

**Institutional Base Salary:** The annual compensation that the applicant institution pays for an employee's appointment, whether that individual's time is spent on research, teaching, patient care, or other activities. Base salary excludes any income that an individual may be permitted to

earn outside of duties to the applicant institution. Base salary may not be increased as a result of replacing institutional salary funds with grant funds.

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

**Key Personnel:** Project key personnel include the Corresponding Principal Investigator and all other Principal Investigators and Co-Principal Investigators, Project Director, and Mentor (in the case of directed research projects involving post-doctoral researcher). These personnel contribute to the scientific development or execution of the project in a substantive way, whether salaries are requested or not.

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

**Overlap, Commitment:** Commitment overlap occurs when any project staff has time commitments exceeding 100 percent. This is the case whether the grant includes salary support for the effort. While information on other support is only requested for the Corresponding Principal Investigator, no individual on the project may have combined commitments more than 100 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 Biomedical Research Program, any branch campuses, centers, or other affiliates of a public university are considered one and the same with that university. Where the number of applications is limited, the university and any branch campuses, centers, or other affiliates must coordinate submission(s) to comply with the limitation.

**Subcontracting:** A contract between the awardee and a third party to perform all or some of the work on the awardee's behalf. This definition does not apply to an awarded consortium unless that consortium is contracting with a third party outside of the organization to perform some or all the work on its behalf.

# III. INSTRUCTIONS- APPLICATION PREPARATION AND SUBMISSION

## 1. General Instructions for Application Submission

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

<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity-announcements/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 Biomedical Research 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 Biomedical Research Program to reject the entire application. Special formatting, scientific notation, pictures, and objects may be included in these documents. However, within the online application form fields such as the Project Title, General Audience Abstract and the Scientific Abstract, use only conventional alphanumeric letters and numbers (i.e. ASCII text) with no drawings, special characters, or symbols.

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

## **B. General Application Guidelines**

1. Applications must be in English.
2. The entire text of all documents uploaded into the online application must be single spaced in an easily readable font. Use standard 11-point type for the text, and no less than 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.

## **C. Budget Guidance**

1. General Instructions: Budget documents are in Excel format and available in the PeerNet application. When calculating the budget summary and narrative be sure to use whole dollars. The budget summary contains totals for each fiscal year and calculations for determining total grant costs. The budget summary must correspond to the calculations in the budget narrative. The budget contains two parts, Attachment V Budget Summary and Budget Narrative:
  - a. The budget summary provides an overview of the estimated budget for the life of the grant by category and by State Fiscal Year (July 1st-June 30th). Do not use calendar months to calculate the budget The grant start date is *Anticipated* to begin April 1, 2024 (FY 23-24 the first three months of the grant) The first fiscal year grant budget should be calculated for three

months. Each remaining year will be for 12-months (July – June) The final budget year should be calculated for nine months.

b. The Budget Narrative provides information regarding how expenses will be used to support the grant. Each budget category requested should include enough detail to justify the expense and should include all calculations for arriving at the totals.

- i. Personnel/Fringe: The name, staff member's role on the project, percent of effort and any other specific rates or cost breakdowns to justify the total personnel and fringe expense. Be sure to account for any cost-of-living increases and include a statement in the narrative. Cost of living increases are limited to three percent per year. Detailed calculations are required to justify the cost for each staff.
- ii. Subcontracting Preapproval of subcontracting is required prior to grant execution. A copy of the proposed or sample subcontract must be provided to the assigned contract manager.
- iii. Indirect Costs: Indirect cost rates may not exceed 15 percent of the total direct costs requested. Direct costs are all expense categories directly associated with the research project. Include calculations for arriving at indirect cost by year. (Ex. Total Operation Cost \$ x % = Total Indirect).

## 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 are converted properly when saving the original documents in PDF format as required.

### 2. Evaluation of Applications

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

#### **A. Administrative Review**

Application materials not received according to the date, time, and location specified in [Table 1](#) will be disqualified.

Each application submitted by the deadline indicated in [Table 1](#) will receive an administrative review verifying mandatory eligibility requirements and the completeness of the application. The administrative review includes a check for potential scientific or budgetary overlap with active or pending projects supported by the Department. The administrative review does not include review of the overall scientific impact.

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

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

### **Peer Review**

Department peer reviewers will assess the overall impact of all qualified/eligible applications. Peer review panels comprise reviewers with expertise in the substance and methodology of the proposed project. Individual reviewers will review and rate applications, including assessing cancer-relatedness, health impact, examining budget requests, and recommending the level of support necessary to complete the work. Reviewers will be nationally prominent individuals drawn from various sectors in the life sciences including universities, government agencies, and industry. Reviewers will be located outside of Florida and will not be associated with any Florida-based public or private entity working in the life sciences. Before being granted access to proposals, every reviewer will be required to accept the terms of a Confidential Nondisclosure Agreement. Reviewers are required to disclose financial interests to the Department, and the Department determines if any disclosed financial interests are conflicts of interests. Reviewers with financial conflicts of interest are not allowed to review applications. Reviewers will receive honoraria for their participation and are expected to set a high standard for scientific excellence. The number and composition of peer review panels will be determined by the number and scientific range of applications received.

### **Overall Impact Score:**

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

- (1) Exceptional – Exceptionally strong with essentially no weaknesses
- (2) Outstanding – Extremely strong with negligible weaknesses
- (3) Excellent – Very strong with only some minor weaknesses
- (4) Very Good – Strong but with numerous minor weaknesses
- (5) Good – Strong but also at least one moderate weakness

- (6) Satisfactory – Some strengths and some moderate weaknesses
- (7) Fair – Some strengths but with at least one major weakness
- (8) Marginal – A few strengths and a few major weaknesses
- (9) Poor – Very few strengths and numerous major weaknesses

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

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

#### **Other Review Considerations:**

Individual peer reviewers will rate the relationship of the project to the advancement toward prevention, diagnosis, treatment, and/or cure of cancer. Peer reviewers will be asked the question “Has the applicant made a compelling case for a strong cancer 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 percent during the individual review stage will progress to the peer review panel stage. Panelists will discuss a set of proposals and provide written comments and numeric scores.

#### **B. Programmatic Review**

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

#### **C. Evaluation Reports**

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

### **3. Notification of Funding Decision**

The applicant organization and Corresponding Principal Investigator will receive written notification via email of the funding decisions as indicated in 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 or designee are final.

### **5. Grantee Requirements**

#### **A. Terms and Conditions**

After awards are made, each grantee must sign a contract, called the “Terms and Conditions,” agreeing to certain legal requirements of the award. The “Terms and Conditions” are non-negotiable and acceptance is required as part of the grant award process. The Department reserves the right to change or modify the “Terms and Conditions” as needed. The “Terms and Conditions” include the post-award schedule of deliverables.

#### **B. Grantee Reporting Requirements**

If the applicant’s proposal is funded, the Grantee must respond to Department requests for information for a period of five (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. I APPENDIX

### 1. Reportable Financial Interests Sample

Florida Department of Health Financial Conflict of Interest in Research	
Principal Investigator:	
Grant Title:	
Grant Number:	
Step 1: Use the following tests to determine if the researcher and the researcher's immediate family, or any other personnel on the grant (sub-investigators and research staff) and their immediate families, have any of the following financial interests related to the research:	
"Immediate Family" means spouse, domestic partner, children, and dependents.	
"Financial Interest Related to the Research" means financial interest in the sponsor, product or service being tested, or competitor of the sponsor.	
<div style="border: 1px dashed black; padding: 5px;"><input type="checkbox"/> 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. <input type="checkbox"/> Compensation of any value related to the research. <input type="checkbox"/> Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement. <input type="checkbox"/> Board or executive relationship in a company (such as a startup company but including publicly traded companies) related to the research, regardless of compensation. <input type="checkbox"/> 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. <input type="checkbox"/> Any other interest that could be affected by the outcome of the research</div>	
If any of the following above conditions are met, provide a description of financial interests related to the research:	
<input type="checkbox"/> 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:	
<ul style="list-style-type: none"><li>- Immediate termination of the grant.</li><li>- Financial consequences, including repayment of all grant funds.</li><li>- Any other action required by state law.</li></ul>	

## 2. Budget Summary and Narrative Sample



### Attachment V Grant Budget Summary

Institution:  Principal Investigator:

Grant Number:  Financial Contact:

BUDGET CATEGORY	FISCAL YEAR ONE 2023-2024 BUDGET (4/1/24-6/30/24)	FISCAL YEAR TWO 2024-2025 BUDGET (7/1/24-6/30/25)	FISCAL YEAR THREE 2025-2026 BUDGET (7/1/25-6/30/26)	FISCAL YEAR FOUR 2026-2027 BUDGET (7/1/26-6/30/27)	FISCAL YEAR FIVE 2027-2028 BUDGET (7/1/27-6/30/28)	TOTAL BUDGET
Personnel / Fringe Benefits	\$0	\$0	\$0	\$0	\$0	\$0
Subcontracting	\$0	\$0	\$0	\$0	\$0	\$0
Equipment	\$0	\$0	\$0	\$0	\$0	\$0
Supplies	\$0	\$0	\$0	\$0	\$0	\$0
Travel	\$0	\$0	\$0	\$0	\$0	\$0
Patient Care	\$0	\$0	\$0	\$0	\$0	\$0
Other Expenses	\$0	\$0	\$0	\$0	\$0	\$0
<b>DIRECT COST SUB-TOTAL:</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>
Indirect Amount:	\$0	\$0	\$0	\$0	\$0	\$0
<b>TOTAL:</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>	<b>\$ -</b>

GRANTEE: FLORIDA DEPARTMENT OF HEALTH

Signature of Authorized Official: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_  
Date: \_\_\_\_\_

Signature of Authorized Official: \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: Deputy Director, Public Health Research  
Biomedical Research Section  
Date: \_\_\_\_\_

- INSTRUCTIONS:**
- The budget must include the entire proposed project cost broken down by category and state fiscal year (July 1 – June 30).
  - Complete the appropriate number of columns below as appropriate for the term of your grant award.
  - The total budget may not exceed the award amount and should be rounded to the nearest **whole dollar amount**.
  - Cost of Living Adjustments are allowable on Fiscal Year Two and forward, not to exceed 3%. Please note, a standard statement has been included on the Budget Narrative.
  - Contractual Costs requires additional forms and prior approval, including a copy of the draft/proposed subcontract.
  - Budget categories may not be altered, combine or revised.
  - Modified Total Direct Cost (MTDC): Hard enter the total for each fiscal year. Formulas will calculate the indirect cost rate x the MTDC amount, not to exceed 15%. Excluded costs should be clearly identified on the Budget Narrative.
  - Indirect costs are limited to no more than 15% of the modified total direct costs requested.
  - Where appropriate, include details that show how the estimated cost was calculated.
  - If changes are needed to adjust direct costs throughout the life of the grant, a budget change request must be submitted and approved.
  - Insert additional rows in the Personnel chart as necessary. The remaining budget category text boxes will expand as you type. Select ALT + Enter to go to the next line.
  - Please contact your assigned Grant Manager for assistance.

## Biomedical Research Grant Budget Narrative

### FISCAL YEAR ONE 2023-2024 (3 Month Budget April - June)

Personnel/Fringe							
Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary/12 months x 3 months x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F+G)
	\$0	0.00%	\$0	0.00%	\$0	\$0	\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
<b>TOTAL PERSONNEL COST:</b>							<b>\$0</b>
<b>Subcontracting</b> <i>(Contractual Services require pre-approval by DOH)</i>							<b>\$0</b>
<b>Equipment</b> <i>(Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)</i>							<b>\$0</b>
<b>Supplies</b> <i>(This line item may be adjusted to bring the budget to the exact award amount)</i>							<b>\$0</b>
<b>Travel</b> <i>(Domestic travel will be reimbursed in accordance with s. 112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)</i>							<b>\$0</b>
<b>Patient Care Costs</b> <i>(Itemize estimated patient care costs)</i>							<b>\$0</b>
<b>Other Expenses</b> <i>(Itemize all Other expense costs)</i>							<b>\$0</b>
<b>Indirect</b> <i>(Show Total Direct Costs x Rate % = \$Total Indirect Costs)</i>							<b>\$0</b>

**Biomedical Research Grant Budget Narrative**  
**FISCAL YEAR TWO 2024-2025 (12 Month Budget)**

Personnel/Fringe							
Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F+G)
	\$0	0.00%	\$0	0.00%	\$0	\$0	\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
<b>TOTAL PERSONNEL COST:</b>							<b>\$0</b>
<b>Subcontracting</b> (Contractual Services require pre-approval by DOH) <span style="float: right;"><b>\$0</b></span>							
<b>Equipment</b> (Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category) <span style="float: right;"><b>\$0</b></span>							
<b>Supplies</b> (This line item may be adjusted to bring the budget to the exact award amount) <span style="float: right;"><b>\$0</b></span>							
<b>Travel</b> (Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night) <span style="float: right;"><b>\$0</b></span>							
<b>Patient Care Costs</b> (Itemize estimated patient care costs) <span style="float: right;"><b>\$0</b></span>							
<b>Other Expenses</b> (Itemize all Other expense costs) <span style="float: right;"><b>\$0</b></span>							
<b>Indirect</b> (Show Total Direct Costs x Rate % = \$Total Indirect Costs) <span style="float: right;"><b>\$0</b></span>							

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

Personnel/Fringe							
Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F+G)
	\$0	0.00%	\$0	0.00%	\$0	\$0	\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
<b>TOTAL PERSONNEL COST:</b>							<b>\$0</b>
<b>Subcontracting</b> <i>(Contractual Services require pre-approval by DOH)</i>							<b>\$0</b>
<b>Equipment</b> <i>(Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)</i>							<b>\$0</b>
<b>Supplies</b> <i>(This line item may be adjusted to bring the budget to the exact award amount)</i>							<b>\$0</b>
<b>Travel</b> <i>(Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)</i>							<b>\$0</b>
<b>Patient Care Costs</b> <i>(Itemize estimated patient care costs)</i>							<b>\$0</b>
<b>Other Expenses</b> <i>(Itemize all Other expense costs)</i>							<b>\$0</b>
<b>Indirect</b> <i>(Show Total Direct Costs x Rate % = \$Total Indirect Costs)</i>							<b>\$0</b>

Biomedical Research Grant Budget Narrative							
FISCAL YEAR FOUR 2026-2027 (12 Month Budget)							
Personnel/Fringe							
Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F+G)
	\$0	0.00%	\$0	0.00%	\$0	\$0	\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
<b>TOTAL PERSONNEL COST:</b>							<b>\$0</b>
<b>Subcontracting</b> (Contractual Services require pre-approval by DOH)							<b>\$0</b>
<b>Equipment</b> (Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)							<b>\$0</b>
<b>Supplies</b> (This line item may be adjusted to bring the budget to the exact award amount)							<b>\$0</b>
<b>Travel</b> (Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)							<b>\$0</b>
<b>Patient Care Costs</b> (Itemize estimated patient care costs)							<b>\$0</b>
<b>Other Expenses</b> (Itemize all Other expense costs)							<b>\$0</b>
<b>Indirect</b> (Show Total Direct Costs x Rate % = \$Total Indirect Costs)							<b>\$0</b>

Biomedical Research Grant Budget Narrative							
FISCAL YEAR FIVE 2027-2028 (8 Month Budget)							
Personnel/Fringe							
Name/Role on Project	Annual Base Salary	% Effort on Project	Project Salary Total (Salary/12 months x 8 months x % Effort)	Fringe %	Fringe Amount (Column D x E)	Fringe Fixed/Flat Rate (if applicable)	Total Personnel & Fringe (Column D + F+G)
	\$0	0.00%	\$0	0.00%	\$0	\$0	\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
			\$0		\$0		\$0
<b>TOTAL PERSONNEL COST:</b>							<b>\$0</b>
<b>Subcontracting</b> (Contractual Services require pre-approval by DOH)							<b>\$0</b>
<b>Equipment</b> (Itemize all equipment costs and include how the equipment will be used toward the research project. Show total cost of category)							<b>\$0</b>
<b>Supplies</b> (This line item may be adjusted to bring the budget to the exact award amount)							<b>\$0</b>
<b>Travel</b> (Domestic travel will be reimbursed in accordance with s.112.061, Florida Statutes. Lodging costs may not exceed \$175 per night)							<b>\$0</b>
<b>Patient Care Costs</b> (Itemize estimated patient care costs)							<b>\$0</b>
<b>Indirect</b> (Show Total Direct Costs x Rate % = \$Total Indirect Costs)							<b>\$0</b>

### 3. Terms and Conditions Sample

#### Florida Department of Health, Grant Agreement for the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program, James and Esther King Biomedical Research Program, and Live Like Bella Initiatives



The Florida Department of Health (Department) requires that a Grant recipient, including its authorized agents, (Grantee) for the William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program; James and Esther King Biomedical Research Program; or Live Like Bella Initiative, comply with the following:

The Funding Opportunity Announcement (FOA), including any amendments, the grant application submitted by the Grantee in response thereto (Application), and the following Grant Terms and Conditions, are hereby incorporated by reference, and made a part of this Agreement:

- a. William G. “Bill” Bankhead, Jr., and David Coley Cancer Research Program Funding Opportunity Announcement: Fiscal Year 2022/2023. Funding Opportunity Announcements can be found at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/foa-archive-page.html>.
- b. James and Esther King Biomedical Research Program Funding Opportunity Announcement: Fiscal Year 2022/2023. Funding Opportunity Announcements can be found at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/foa-archive-page.html>.
- c. Live Like Bella Pediatric Cancer Research Initiative Funding Opportunity Announcement: Fiscal Year 2022/2023. Funding Opportunity Announcements can be found at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/foa-archive-page.html>.

#### GRANT TERMS AND CONDITIONS

1. **Compliance with Laws:** Grantee must comply with the provisions outlined in those documents, all applicable federal and State of Florida laws, rules, and regulations.
2. **Grant Period and Award:** The grant titled, «*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, Grant Information. The grant period will include the original term of the grant and all approved extensions. Awards, extensions, and payments will be made contingent upon satisfactory project performance and compliance with this Agreement. **The Department’s performance and obligation to pay under this Agreement are contingent upon annual appropriation by the Florida Legislature and the availability of funds.**
3. **Starting the Grant Project:** This project may only begin with: executed Terms and Conditions; a Department approved budget; a conflict of interest form signed by the Principal Investigator (PI) and

the following documents completed and submitted to the Department, as applicable: an approved management plan; an Institutional Review Board (IRB) approval(s); an Institutional Animal Care and Use Committee (IACUC) approval(s); an Institutional Biosafety Committee (IBC) approval(s); and a Radiation Safety Review(s). Grantee agrees to the following:

- a. Starting the Grant Project: A five percent reduction will be assessed on that invoice or the grant terminated, at the Department's sole discretion, if the grant project has not started within three months after the Agreement execution date.
- b. Institutional Authorization(s): If the grant project requires the use of human subjects or vertebrate animals, recombinant DNA, stem cells, or radiation; the Grantee must submit to the Department the approval(s), and any applicable protocol(s) and consent form(s), within 10 days from execution of this Agreement, for all institutional authorizations including, but not limited to, an IRB, an IACUC, and an IBC approval, and a Radiation Safety Review. Any institutional authorization must include the grant title exactly as it appears in Section 2. Grant Period and Awards, of this Agreement. For additional details, review Section 26 below regarding the use of human subjects, Section 27 below regarding use of vertebrate animals, Section 28 below regarding recombinant nucleic acid, Section 29 below regarding stem cells, and Section 30 below regarding radiation safety reviews. Any changes or modifications to institutional authorizations, protocols, or consent forms must be submitted to the Department no later than 10 working days after the approved change or modification. Failure to provide the Department of any approvals or changes to IRB, IACUC, or IBC approvals, or a Radiation Safety Review, will result in a 10 percent financial consequence being assessed on that invoice.
- c. Monthly Updates: Grantee must update the Department via email each month regarding the status of all applicable regulatory applications prior to receiving institutional authorization. Failure to update the Department as specified will result in a financial consequence of 10 percent being assessed on that invoice. Once all applicable institutional authorizations are received, and the Department has been sent a final update stating that all applications have been approved, the Grantee will no longer need to provide the Department with monthly updates.
- d. Pending Institutional Authorizations: The Grantee must request, in writing, from the Department's Grant Manager, authority to begin a portion of the grant project that does not deal with human subjects, vertebrate animals, recombinant DNA, stem cells, or radiation pending institutional authorization(s).
- e. Grant Administration Manual: For Grantees, an important reference document is the Grant Administration Manual, which contains Department policies as well as the procedures necessary for compliance with those policies. It is organized around a typical grant lifecycle. The Grant Administration Manual can be found on the Department's website in the Grant Management Forms Library and Other Resources at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.

#### **4. Scope of Work and Project Adjustments:**

- a. Grantee must complete all work as described in the approved application.
- b. Any changes or adjustments in the designs, aims, or research plans as proposed in the application; any changes requiring IRB, IACUC, or IBC approvals, or Radiation Safety Review; 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 will result in either a 20 percent financial consequence being assessed on that invoice or termination of the grant, at the Department's sole discretion.

- 5. Required Documentation:** Grantee must provide reports to the Department describing the impact of the research on health outcomes; scientific impact such as publications in peer-review journals, presentations, collaborations, or patents; and any subsequent additional grant funding related to the research subject. Failure to comply with the following requirements will result in either a 10 percent financial consequence being assessed on that invoice or grant termination, at the Department's sole discretion:

  - a.** Grantee must prepare quarterly financial reports and narrative progress reports, which include a description of the impact of the research on health outcomes and other deliverables as outlined in Attachment II. Reports must be submitted to the Department within one month of the end of each quarter and received no later than close of business 5:00 p.m., E.S.T. on the dates outlined in Attachment II. Reports must be prepared in the format specified by the Department. Failure to use the correct report templates will result in delay of payment. Quarterly report templates are provided on the Department's website located at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.
  - b.** Grantee must prepare annual and final Florida Legislative Progress Reports to be used in the preparation of the statutorily required annual report to the Florida Legislature and Governor. Grantee will make all reasonable efforts to assist the Department in gathering data required for reporting to the Florida Legislature and Governor pursuant to section 381.922(6) or 215.5602(10), Florida Statutes, and other laws, as applicable, both during and after the grant period. Upon request, Grantee agrees to report to the Department 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, peer-reviewed journal articles, databases, additional grants and monies received, postsecondary educational institutional involvement, patents, inventions disclosures, collaborations, and copyrights. The narrative report is intended for a general audience and should be limited to 500 words. The report is due annually by July 31. The report template is provided on the Department's website located at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.
- 6. Grant Project Deliverables:** Failure to provide the deliverables specified in Attachment II, Schedule of Deliverables and Payments, will result in a financial consequence of 10 percent being assessed on that invoice or grant termination, at the Department's sole discretion.
- 7. Fiscal Quarters:** There are four quarters in the State fiscal year, consisting of three months each. The quarters are as follows: Quarter 1 is July 1 through September 30; Quarter 2 is October 1 through December 31; Quarter 3 is January 1 through March 31; and Quarter 4 is April 1 through June 30.
- 8. Payment:** This grant has a fixed payment schedule as shown in Attachment II. Payments will be contingent on Grantee complying with this Agreement and the following:

  - a.** Grantee must request payment using the Department's invoice form, located at <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>. Only allowable expenditures will be reimbursed by the Department. If the Department or the Department of Financial Services (DFS) requires additional information regarding reported expenditures, the Grantee must provide the requested information no later than

three working days from the time of notification from the Department's Grant Manager. Failure to provide additional requested information within three working days will result in a 10 percent financial consequence being assessed on that invoice.

b. Grantee will only be paid for satisfactory and timely completion of the deliverables. Payment of the final invoice for a grant will take place after the end of the grant period and all required deliverables have been received and approved by the Department. A final reconciliation of expenditures during the life of the grant will impact the final invoice. The final payment will total all reconciled grant expenditures.

c. Total payment received under this Agreement cannot exceed the total award amount.

**9. Key Personnel Requirements and Adjustments:** Project key personnel include the Corresponding Principal Investigator, Co-PI(s), 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, including all Department Biomedical Research grants, is not permitted.

b. Grantee must establish a system to track work effort commitments of all key personnel. Effort certification documentation must indicate the committed or actual work effort expended on the grant during the grant period as well as the percentage of effort performed for all deliverables. 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, Co-PI(s), and Mentor changes. The Grantee must complete and submit to Department via email the Key Personnel Change/Change in Effort form for any changes to Project Director, Corresponding Principal Investigator, Co-PI(s), and Mentor. This form can be found at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>. Changes to any of these roles without the prior written approval of the Department will result in a 10 percent financial consequence being assessed on that invoice or grant termination, at the Department's sole discretion.

d. Replacement of or reduction in the effort of the Project Director or Co-PI(s) are not allowed within the first year and may not be decreased more than 10 percent within any one year of the grant period. The amount of effort of the Project Director or Co-PI(s) must remain consistent with the approved budget and any approved changes.

**10. Budget:** The current approved budget is the Attachment V.a., Budget Form, approved by the Department at the beginning of the grant and includes any approved budget changes.

a. The Department will reimburse Grantee for allowable, reasonable, and necessary costs as detailed in Attachment V.b., Budget Narrative.

b. Budget changes may be made anytime during the life of the grant. Overspending in any category must be justified and approved by the Department prior to making such expenditure. The Grantee must complete the Budget Change Request form and submit it to the Department's Grant Manager via email. The Budget Change Request form can be found at <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.

[resources/forms-library.html](#). Approved revisions to the grant budget will become effective upon approval by the Department.

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

**11. No-Cost Extension:** Requests for No-Cost Extension must meet the following requirements:

- a. Grantee must submit the Department's Request for No-Cost Extension form, including the completed Cumulative Grant Progress Report, to the Department's Grant Manager no later than three months prior to the end date of the grant specified in Attachment II. Any no-cost extension request received after the three-month deadline will not be considered by the Department for approval.
- b. Grantee will not be eligible for more than one, six-month, no-cost extension. Grants awarded for 54 months are not eligible for a no-cost extension.
- c. No additional grant funding will be provided to the Grantee if the no-cost extension request is approved by the Department.

**12. Property and Equipment:** Property and equipment is defined as non-expendable, tangible property having a useful life of more than one year with a cost of \$5,000 or more. 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. Grantee must ensure the following:

- a. All approved property and equipment must be purchased and received prior to the last three months 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. For research institutions not covered under Chapter 1000, Florida Statutes, equipment no longer deemed to be useful will remain state property and must be transferred or donated to a state agency or public university for redistribution or disposition.

**13. Fiscal Accountability:** 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. Grantee must not commingle grant funds with other personal or business accounts. Grantee must not use grant funds to supplant or replace funds from other resources.
- b. Grantee must maintain sufficient documentation of all grant expenditures as proof that such expenditures are allowable, reasonable, and necessary for the work performed under this agreement. Grantee may not charge the Department for the value of donated goods, services, or facilities.
- c. 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 approved 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. In order to implement appropriations in the General Appropriations Act for State travel and notwithstanding section 112.061, Florida Statutes, costs for lodging associated with a meeting, conference, or convention organized or sponsored in whole or in part by a state agency or the judicial branch may not exceed the current State of Florida conference travel rates. For all other travel, the lodging travel rate is \$175.00. The Grantee will not be reimbursed for reservations made through third party travel sites (e.g., Booking.com, Expedia, Orbitz). Grantees must submit a travel voucher form in every quarter in which they charged travel to their grant budgets. Travel is only approved within the United States, including its territories. The State of Florida Voucher for Reimbursement of Travel Expenses should be used for all travel-related expenses unless the Grantee's institutional travel voucher or expenditure form has received prior approval from the DFS. Support documentation for all travel-related expenses is needed, e.g., receipts for flight, hotel, parking, rental car, fuel, ground transportation, as well as registration, meeting agenda or schedule, and copy of any presentation made. Do not use acronyms or abbreviations on travel forms or documentation. The State of Florida Voucher for Reimbursement of Travel Expenses may be found at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.

**14. Return of Funds:** 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 three months of grant end date. In the event 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, or goods and services of the Grantee that are relevant to this grant, and 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 Grantee a written report of its findings and may include written recommendations with regard to Grantee's performance of the Terms and Conditions of this grant. Grantee will correct all noted deficiencies identified by the Department within the specified period of time set forth in the recommendations. 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) Grantee being

deemed in breach or default of this agreement; 2) the withholding of payments to 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 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, 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. Public Records:** The Grantee must keep and maintain public records, as defined in Chapter 119, Florida Statutes that are required by the Department to perform the services required by the grant. Upon request from the Department's custodian of public records, provide the Department with a copy of the requested public records or allow the records to be inspected or copied within a reasonable time at a cost that does not exceed that provided in Chapter 119, Florida Statutes, or as otherwise provided by law. Ensure that public records that are exempt or that are confidential and exempt from public record disclosure are not disclosed, except as authorized by law for the duration of the grant term and following completion of the grant if Grantee does not transfer the public records to the Department. Upon completion of the grant, transfer to the Department at no cost, all public records in possession of Grantee or keep and maintain public records required by the Department to perform the grant services. If Grantee transfers all public records to the Department upon completion of the grant, Grantee will destroy any duplicate public records that are exempt or confidential and exempt. If Grantee keeps and maintains public records upon completion of the grant, Grantee will meet all applicable requirements for retaining public records. All records stored electronically must be provided to the Department, upon request of the Department's custodian of public records, in a format that is compatible with the information technology systems of the Department. The Department may unilaterally terminate this grant if Grantee refuses to allow access to all public records made or maintained by Grantee in conjunction with this grant, unless the records are exempt from section 24(a) of Art. I of the State Constitution and section [119.07\(1\)](#), Florida Statutes.

**If the Grantee has questions regarding the application of Chapter 119, Florida Statutes, to the Grantee's duty to provide public records relating to this Agreement, contact the custodian of public records at (850)245-4005, [PublicRecordsRequest@flhealth.gov](mailto:PublicRecordsRequest@flhealth.gov) or 4052 Bald Cypress Way, Bin A02, Tallahassee, FL 32399.**

- 19. Financial Overlap:** 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 institutional awards (not included are training awards, prizes, or gifts). 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. Grantee is responsible for monitoring changes in other support for project key personnel to avoid financial overlap. Grantee is responsible for notifying the Department of such changes and for resolving overlap or requesting an amendment to prevent overlap. If financial overlap is due to receipt of an award from another funding source during the grant period, Grantee must notify the Department within 48 hours and resolve the overlap by: a) modifying the start date or project aims of the new award to eliminate the overlap or b) relinquishing one of the awards. Updated information on other support may be requested by and must be provided to the Department at any time during the grant period. Failure to notify the Department within 48 hours will result in a financial consequence of 20 percent on the invoice.

- 20. Financial Conflict of Interest:** The Grantee must report to the Department any reportable interests, regardless of any conflict-of-interest procedures at Grantee's institution, at the time of the application and before the grant starts. 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. Grantee must inform the Department of any conflict-of-interest management plan required by Grantee's institution prior to starting research. The Department may require an additional management plan if the plan developed by Grantee's institution is not acceptable to the Department. If a reportable interest as defined by the Department arises after the grant starts, Grantee must notify the Department within 48 hours. Failure to notify the Department within 48 hours will result in a financial consequence of 10 percent on the invoice.
- 21. Assignment, Subcontracts, and Sub-grants:** The Grantee must neither assign any 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 must be null and void. No subcontracts, or sub-grants will be authorized that involve researchers outside of the State of Florida. However, the Department may make exceptions, if the service is essential and only provided outside the state, and if the subcontract or sub-grant amount is less than 10 percent of the grant award amount. 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 Grantee to subcontract part of the work contemplated under this grant, including entering into subcontracts with vendors for services and commodities, it is understood by Grantee that the Department will not be liable to the subcontractor for any expenses or liabilities incurred under the subcontract and Grantee will be solely liable to the subcontractor for all expenses and liabilities incurred under the subcontract. To the extent permitted by Florida Statutes, Grantee, at its expense, will defend the Department against such claims. The Department must be entitled to assign or transfer, in whole or in part, its rights, duties, or obligations under this agreement to another governmental agency in the State of Florida upon giving prior written notice to Grantee.
- 22. Confidentiality:** The Grantee must maintain confidentiality of all data, files, documents, papers, electronic storage media, and records, including client records, and must protect the privacy of human subjects related to this grant and all services provided. 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, 45 CFR 160, 162, and 164, 21 CFR 45, and 21 CFR 56.111) 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. Failure to report any breach of confidentiality to the Department within 48 hours will result in a financial consequence of 10 percent on the invoice.

**23. Publications, Presentations, Patents, or Printing of Reports:** Any publications, presentations, patents, printed reports, materials designed for use by the general public (e.g., educational pamphlets), or resulting research findings related to this grant must acknowledge the appropriate funding source: Florida Department of Health, Public Health Research, Biomedical Research Program. Grantee must notify the Department of all publications, presentations, patents, printed reports, materials designed for use by the public, and research findings as a result of this grant both during the grant period and for a period of six years after the grant ends. Return on Investment surveys will be sent to prior grantees for completion which measures the long-term impact of the research grant funds. The Grantee is to provide the Department a copy of each peer-reviewed journal article that is published. Further, if research is presented at a conference, the presentation, poster, and abstract should be submitted to the Department. If the presentation was scientific, a summary should be developed and submitted that can be understood by and provided to the public.

**24. Public Access:** The following provisions ensure public access to materials resulting from this grant:

- 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 material transfer agreements.
- b. In concert with the National Institutes of Health (NIH) notice NOT-OD-08-033, Grantee must submit or have submitted for them to the United States' National Library of Medicine's PubMed Central, an electronic version of their final, peer-reviewed manuscripts upon acceptance of the publication, to be made publicly available no later than 12 months after the official date of publication, in a manner consistent with copyright law.

**25. Patents, Copyrights, Trademarks, and Royalties:** The following provisions will apply to all inventions, including intellectual property created by this grant:

- a. All inventions will be the property of Grantee or business partner if a written agreement has been executed; and Grantee will retain the entire right, title, and interest to such.
- b. Grantee will grant the State of Florida 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 must disclose all inventions to the Department in the applicable quarterly report of patent application or any licensing event and will subsequently report on commercialization progress regarding patenting (filing dates and issue dates), licensing, and commercialization events. Noncompliance will result in a financial consequence of 10 percent on the invoice.
- 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 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,

Grantee must furnish the Department with a description of said property and a copy of any licensing obtained.

- f. During the grant period the Grantee must report to the Department, any progress in securing or exploiting such inventions, trademarks, copyrights, or patents, and for a period of six years after the grant ends.
- 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.

**26. Policy Regarding Scientific Misconduct:** The following provisions must 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, 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 1-month of the imposition of the administrative action. Noncompliance will result in a financial consequence of 20 percent on the invoice or grant termination.
- b. Each eligible institution that receives or applies for a grant must certify establishment of administrative policies consistent with 42 CFR 50, Subpart A, "*Responsibility of 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.*"

**27. Human Subjects:** The following provisions must 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 must obtain, maintain, and provide to the Department an active Institutional Review Board (IRB) approval letter before project work can begin. The approval letter must include Corresponding Principal Investigator's name, grant title exactly as it appears in these Terms and Conditions, approval date, expiration date, and the signature of the approving authority chairperson.
- c. 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.

- d. Grantees are required to obtain and maintain approval from an IRB accredited by the Association for Accreditation of Human Research Protection Programs (AAHRPP), or an IRB acceptable to the Department, within two months of notice of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department.
- e. 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 subjects. This does not require any particular party to be responsible for such care; it requires that it be made clear to subjects through the informed consent document/process who will provide medical care and who will be responsible to pay for it, should a subject experience a research-related injury.
- f. 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 subjects or others, and any suspension or termination of IRB approval. Grantee's IRB must report to the Department when reporting to federal officials any serious or continuing non-compliance or unanticipated problem involving risks to subjects or others. Noncompliance will result in a financial consequence of 10 percent on the invoice or grant termination.
- g. 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.
- h. Grantee must comply with NOT-OD-18-014: "*NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.*"
- i. Research subjects can receive participation payments. Grantees must provide the page of the approved IRB protocol that indicates the research participant payment form and amount. Participant payment distribution logs with all personal information redacted will be required with each invoice. The logs will serve as an accounting of incentives given to research subjects each quarter. A summary of the log must be included with each invoice that provides the total number of participant visits for the quarter, the unit cost for participant payments, visit type, and the total cost for participant payments for each quarter. An example of this required documentation can be found at: <http://www.floridahealth.gov/provider-and-partner-resources/research/grant-programs-resources/forms-library.html>.

**28. 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 IACUC approval before project work can begin. The verification must include Corresponding Principal Investigator name, the exact grant title, approval and expiration dates, and signature of the approving authority chairperson.

- c. Grantee must 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. Noncompliance will result in a financial consequence of 10 percent on the invoice.
  - 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.
- 29. Recombinant Nucleic Acid:** All research involving Recombinant Nucleic Acid techniques must meet the requirements of the *“NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules.”* The Corresponding Principal Investigator is responsible for verifying if IBC approval is warranted.
- 30. Stem Cells:** All research involving human stem cells must meet the requirements of the *“National Institutes of Health Guidelines for Human Stem Cell Research.”* The Corresponding Principal Investigator is responsible for verifying if IBC approval is warranted.
- 31. Radiation Safety Review:** All research involving radiation must meet the requirements of the *“NIH Human Research Protection Program,”* in addition to any grantee radiation safety requirements. The Corresponding Principal Investigator is responsible for verifying if a Radiation Safety Review is warranted.
- 32. Lobbying:** Pursuant to sections 11.062 and 216.347, Florida Statutes, no portion of grant funds will be used for lobbying.
- 33. Insurance:** 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, Grantee accepts full responsibility for identifying and determining the type(s) and extent of liability insurance necessary to provide reasonable financial protections for Grantee and the clients to be served under this grant, if any. Upon execution of this grant, upon request, 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.

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

- a. 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 grant that evidences that expenditures are:
  - 1) Allowable under the grant and applicable laws, rules, and regulations;
  - 2) Reasonable; and
  - 3) Necessary for Grantee to fulfill the obligations under these Terms and Conditions.
- b. The aforementioned documentation is subject to review by the Department and the State Chief Financial Officer and Grantee will comply timely with any requests for documentation.

**35. Termination:** This Agreement may be terminated in the following manner:

- a. Termination at Will: This Agreement may be terminated by either party upon no less than one month written notice provided to the other party, unless a lesser time is agreed to in writing by the parties.
- b. Termination due to Lack of Funds: 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 Grantee. The notice must 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.
- c. Payments: In the event this Agreement is terminated, Grantee will be compensated for any deliverables completed prior to the termination effective date.
- d. Termination for Breach: 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 Grantee.

**36. Indemnification:** Unless Grantee is an agency or subdivision of the State of Florida or a public college or university as identified in Chapter 1004, Florida Statutes, Grantee will be liable for and must 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 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 Grantee not liable will excuse performance of this provision.

Nothing in this Agreement is intended to serve as a waiver of sovereign immunity, nor must 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.

### **37. 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 must 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 must 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 must be deemed a waiver of any default hereunder.
- c. Modifications of provisions of this agreement must only be valid when they have been reduced to writing and duly signed by both parties.
- d. Any dispute concerning performance of this Agreement or payment hereunder shall be decided by the Department in writing and submitted to the Grantee for review. The decision is final unless the Grantee submits a written objection to the Department within 10 calendar days from receipt of the decision. Upon receiving an objection, the Department shall provide an opportunity to resolve the dispute by mutual agreement between the parties using a negotiation process to be completed within seven calendar days from the Department's receipt of the objection. Completion of the negotiation process is a condition precedent to any legal action by the Grantee or the Department concerning this Agreement. Nothing contained in this section is construed to limit the parties' rights of termination pursuant to section 35., above.

### **38. Contact:**

- a. The Department is now using an online grant management system, PeerNet. Sign into PeerNet (<https://peernet.orau.org>) using your existing login and password. All required forms for this grant are located in PeerNet. All Principal Investigators will be able to add "contributors," including all post-execution contacts, who can upload documents for the grant they are assigned. All correspondence relating to contractual matters should be directed through PeerNet.
- b. A Vendor Ombudsman has been established within DFS, whose duties include acting as an advocate for Grantees who may be experiencing problems in obtaining timely payment(s) from a state agency. The Vendor Ombudsman may be contacted at (850) 413-5516 or (800) 342-2762, the DFS Consumer Hotline.

### **39. Background Screening Requirements and Drug Screening Requirements:**

- a. Background Screening Requirements: In the Department's sole and exclusive discretion, it may determine that background screening of some or all of Grantee's officers, agents, employees, subcontractors, or assignees is necessary (collectively individuals). In the event background screenings are required under this agreement, Grantee agrees to the following:

1. Conduct background screenings in accordance with Chapter 435, Florida Statutes, using level 2 screening standards.
2. Provide the Department with a written attestation confirming that the individual has completed and cleared the level 2 background screening.
3. Not allow the individual to begin work under this Agreement until that individual has been cleared by the Department.
4. Be responsible for any costs incurred in meeting this screening requirement, unless otherwise specified by the Department in writing.

**b. Drug Screening Requirements:** Grantee agrees to the following:

1. If the Grantee's officers, agents, employees, subcontractors, or assignees (collectively "individuals") are assigned to work in a Department designated Safety-Sensitive Class and/or Position, under this Agreement, then a drug test must be performed prior to the individual being allowed to start work under this Agreement. If an individual has already been screened by the Provider, then a written attestation confirming that the individual has completed and cleared the drug screening must be submitted to the Department prior to contract execution. If an individual has not been drug screened, notify the Department immediately. No individual can begin work under this Contract until they have been cleared by the Department.
2. If at any time while performing services under this Contract reasonable suspicion exists to believe that the Provider's staff, which includes, but is not limited to, Provider's officers, agents, employees, subcontractors, or assignees, are under the influence of or impaired by drugs, the Department reserves the right to require the individual to undergo drug testing. The Department may require the individual to cease performing services pending drug test results. In the event of a positive drug test, the Provider must notify the Department in writing and at which time the Department may request a replacement of equal or superior skills and qualifications of the prior individual.
3. Be responsible for any costs associated with meeting this screening requirement, unless otherwise specified in writing by the Department.

**40. Public Entity Crime, Discriminatory Vendor, and Scrutinized Companies:**

- a. Public Entity Crime: Pursuant to section 287.133, Florida Statutes, the following restrictions are placed on the ability of persons convicted of public entity crimes to transact business with the Department: When a person or affiliate has been placed on the convicted vendor list following a conviction for a public entity crime, he or she may not submit a bid on a contract to provide any goods or services to a public entity, may not submit a bid on a contract with a public entity for the construction or repair of a public building or public work, may not submit bids on leases of real property to a public entity, may not be awarded or perform work as a contractor, supplier, subcontractor, or consultant under a contract with any public entity, and may not transact business with any public entity in excess of the threshold amount provided in section 287.017, Florida Statutes, for CATEGORY TWO for a period of 36 months from the date of being placed on the convicted vendor list.

- b. **Discriminatory Vendor:** Pursuant to section 287.134, Florida Statutes, the following restrictions are placed on the ability of persons convicted of discrimination to transact business with the Department: When a person or affiliate has been placed on the discriminatory vendor list following a conviction for discrimination, he or she may not submit a bid on a contract to provide any goods or services to a public entity, may not submit a bid on a contract with a public entity for the construction or repair of a public building or public work, may not submit bids on leases of real property to a public entity, may not be awarded or perform work as a contractor, supplier, subcontractor, or consultant under a contract with any public entity, and may not transact business with any public entity in excess of the threshold amount provided in section 287.017, Florida Statutes, for CATEGORY TWO for a period of 36 months from the date of being placed on the discriminatory vendor list.
  
  - c. **Scrutinized Companies:** Pursuant to section 287.135, Florida Statutes, if Grantee is found to have been placed on the Scrutinized Companies that Boycott Israel List or is engaged in a boycott of Israel, regardless of the Agreement amount, this Agreement may be terminated at the option of the Department.
- 41. Annual Compensation Report:** Grantee must submit Attachment III, Annual Compensation Report, including the most recent Internal Revenue Services (IRS) Form 990, detailing the total compensation for the providers' executive leadership teams, to the Department's Grant Manager no later than January 31 of each contract year. Total compensation shall include salary, bonuses, cashed-in leave, cash equivalents, severance pay, retirement benefits, deferred compensation, real-property gifts, and any other payout. If the Provider is exempt from filing IRS Form 990, submit the Attachment III, without including the IRS Form 990, to the Department. All Annual Compensation Reports must indicate what percent of compensation comes directly from State or Federal funding allocations given to the Provider. In addition, the Provider, by executing this contract, which includes any subsequent amendments, agrees to inform the Department of any changes in total executive compensation specified in the Provider's submitted Annual Compensation Reports.
- 42. E-Verify Requirement:** Effective January 1, 2021, Grantee is required to use the U.S. Department of Homeland Security's E-Verify system to verify the employment eligibility of all newly hired employees used by the Grantee under this Agreement, pursuant to section 448.095, Florida Statutes. Also, the Grantee must include in related subcontracts, if authorized under this Agreement, a requirement that subcontractors performing work or providing services pursuant to this Agreement use the E-Verify system to verify employment eligibility of all newly hired employees used by the subcontractor for the performance of services under this Agreement. The subcontractor must provide the Grantee with an affidavit stating that the subcontractor does not employ, contract with, or subcontract with an unauthorized alien. The Grantee must maintain a copy of such affidavit for the duration of the Agreement. If the Department has a good faith belief that a subcontractor knowingly violated section 448.095(1), Florida Statutes, and notifies the Grantee of such, but the Grantee otherwise complied with this statute, the Grantee must immediately terminate the agreement with the subcontractor.

In Witness Thereof, the parties have caused this \_\_\_ page Agreement to be executed by their undersigned, duly authorized officials, and attest to have read the above Agreement and agree to the terms contained within it.

**GRANTEE:**  
**«Organization»**

\_\_\_\_\_  
«SRO»  
«SRO\_Title», «SRO\_office»

\_\_\_\_\_ Date

**FLORIDA DEPARTMENT OF HEALTH:**

\_\_\_\_\_  
Department of Health Signatory

\_\_\_\_\_ Date

## Attachment I Grant Information

 <b>Florida Biomedical Research Programs Terms and Conditions</b>	
Program:	«Grant_Program»
Program CSFA #:	«Program_CSFA»
Grant Number:	«Grant_Number»
Vendor Identification Number:	«Vendor_Identification_Number»
Grant Category:	«Grant_Category»
Grantee:	«Organization»
Principal Investigator:	«PI»
Grant Title:	«Title»
Grant Abstract:	«Abstract»
Grant Period:	«Grant_Period»
Grant Term:	«Grant_TermMonths» months
Total Grant Award:	«Award_Amount»

## Attachment II Schedule of Deliverables and Payments

 <b>Florida Biomedical Research Programs</b> <b>Terms and Conditions</b> 			
<b>«Grant_Program»</b> <b>Grant Title: «Title»</b>			
Del. #	Deliverable	Period Covered	Due Dates by COB 5:00 p.m., E.S.T.
<b>FISCAL YEAR 2022-2023</b>			
1	<ul style="list-style-type: none"> <li>• 4<sup>th</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 4<sup>th</sup> Quarter Financial Report</li> <li>• 4<sup>th</sup> Quarter Expenditure Report</li> <li>• 4<sup>th</sup> Quarter Progress Report</li> <li>• Proof of Liability Insurance</li> <li>• Florida Legislative Progress Report (Reference page 3,5. b.)</li> </ul>	<p style="text-align: center;">April 1, 2024 – June 30, 2024</p> <p style="text-align: center;">Legislative Report Period: April 1, 2024 – June 30, 2024</p>	July 31, 2024
<b>FISCAL YEAR 2024-2025</b>			
2	<ul style="list-style-type: none"> <li>• 1<sup>st</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 1<sup>st</sup> Quarter Financial Report</li> <li>• 1<sup>st</sup> Quarter Expenditure Report</li> <li>• 1<sup>st</sup> Quarter Progress Report</li> </ul>	July 1, 2024 – September 30, 2024	October 31, 2024
3	<ul style="list-style-type: none"> <li>• 2<sup>nd</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 2<sup>nd</sup> Quarter Financial Report</li> <li>• 2<sup>nd</sup> Quarter Expenditure Report</li> <li>• 2<sup>nd</sup> Quarter Progress Report</li> </ul>	October 1, 2024 – December 31, 2024	January 31, 2024
4	<ul style="list-style-type: none"> <li>• 3<sup>rd</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 3<sup>rd</sup> Quarter Financial Report</li> <li>• 3<sup>rd</sup> Quarter Expenditure Report</li> <li>• 3<sup>rd</sup> Quarter Progress Report</li> </ul>	January 1, 2025 – March 31, 2025	April 30, 2025
5	<ul style="list-style-type: none"> <li>• 4<sup>th</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 4<sup>th</sup> Quarter Financial Report</li> <li>• 4<sup>th</sup> Quarter Expenditure Report</li> <li>• 4<sup>th</sup> Quarter Progress Report</li> <li>• Proof of Liability Insurance</li> <li>• Florida Legislative Progress Report (Reference page 3,5. b.)</li> </ul>	<p style="text-align: center;">April 1, 2025 – June 30, 2025</p> <p style="text-align: center;">Legislative Report Period: July 1, 2024 – June 30, 2025</p>	July 31, 2025

<b>Del. #</b>	<b>Deliverable</b>	<b>Period Covered</b>	<b>Due Dates by COB 5:00 p.m., E.S.T.</b>
	<b>FISCAL YEAR 2025-2026</b>		
6	<ul style="list-style-type: none"> <li>• 1<sup>st</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 1<sup>st</sup> Quarter Financial Report</li> <li>• 1<sup>st</sup> Quarter Expenditure Report</li> <li>• 1<sup>st</sup> Quarter Progress Report</li> </ul>	July 1, 2025 – September 30, 2025	October 31, 2025
7	<ul style="list-style-type: none"> <li>• 2<sup>nd</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 2<sup>nd</sup> Quarter Financial Report</li> <li>• 2<sup>nd</sup> Quarter Expenditure Report</li> <li>• 2<sup>nd</sup> Quarter Progress Report</li> </ul>	October 1, 2025 – December 31, 2025	January 30, 2026
8	<ul style="list-style-type: none"> <li>• 3<sup>rd</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 3<sup>rd</sup> Quarter Financial Report</li> <li>• 3<sup>rd</sup> Quarter Expenditure Report</li> <li>• 3<sup>rd</sup> Quarter Progress Report</li> </ul>	January 1, 2026 – March 31, 2026	April 30, 2026
9	<ul style="list-style-type: none"> <li>• 4<sup>th</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 4<sup>th</sup> Quarter Financial Report</li> <li>• 4<sup>th</sup> Quarter Expenditure Report</li> <li>• 4<sup>th</sup> Quarter Progress Report</li> <li>• Proof of Liability Insurance</li> <li>• Florida Legislative Progress Report (Reference page 3,5.b.)</li> </ul>	April 1, 2026 – June 30, 2026  Legislative Report Period: July 1, 2025 – June 30, 2026	July 31, 2026
	<b>FISCAL YEAR 2026-2027</b>		
10	<ul style="list-style-type: none"> <li>• Invoice for «Invoice_Amount»</li> <li>• 1<sup>st</sup> Quarter Financial Report</li> <li>• 1<sup>st</sup> Quarter Expenditure Report</li> <li>• 1<sup>st</sup> Quarter Progress Report</li> </ul>	July 1, 2026 – September 30, 2026	October 30, 2026
11	<ul style="list-style-type: none"> <li>• 2<sup>nd</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 2<sup>nd</sup> Quarter Financial Report</li> <li>• 2<sup>nd</sup> Quarter Expenditure Report</li> <li>• 2<sup>nd</sup> Quarter Progress Report</li> </ul>	October 1, 2026 – December 31, 2026	January 29, 2026
12	<ul style="list-style-type: none"> <li>• 3<sup>rd</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 3<sup>rd</sup> Quarter Financial Report</li> <li>• 3<sup>rd</sup> Quarter Expenditure Report</li> <li>• 3<sup>rd</sup> Quarter Progress Report</li> </ul>	January 1, 2027 – March 31, 2027	April 30, 2027
13	<ul style="list-style-type: none"> <li>• 4<sup>th</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 4<sup>th</sup> Quarter Financial Report</li> <li>• 4<sup>th</sup> Quarter Expenditure Report</li> <li>• 4<sup>th</sup> Quarter Progress Report</li> <li>• Proof of Liability Insurance</li> <li>• Florida Legislative Progress Report (Reference page 3,5.b.)</li> </ul>	April 1, 2027 – June 30, 2027  Legislative Report Period: July 1, 2026 – June 30, 2027	July 30, 2027

Del. #	Deliverable	Period Covered	Due Dates by COB 5:00 p.m., E.S.T.
	<ul style="list-style-type: none"> <li>• <b>FISCAL YEAR 2027-2028</b></li> </ul>		
	<p><b>IF REQUESTING A 6-MONTH NO-COST EXTENSION SUBMIT THE FOLLOWING:</b></p> <ul style="list-style-type: none"> <li>• No-Cost Extension Request Form</li> <li>• Cumulative Grant Progress Report</li> </ul>	Life of the Grant	October 29, 2027
14	<ul style="list-style-type: none"> <li>• 1<sup>st</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 1<sup>st</sup> Quarter Financial Report</li> <li>• 1<sup>st</sup> Quarter Expenditure Report</li> <li>• 1<sup>st</sup> Quarter Progress Report</li> </ul>	July 1, 2027 – September 30, 2027	October 30, 2027
15	<ul style="list-style-type: none"> <li>• 2<sup>nd</sup> Quarter Invoice for «Invoice_Amount»</li> <li>• 2<sup>nd</sup> Quarter Financial Report</li> <li>• 2<sup>nd</sup> Quarter Expenditure Report</li> <li>• 2<sup>nd</sup> Quarter Progress Report</li> </ul>	October 1, 2027 – December 31, 2027	January 28, 2028
16	<ul style="list-style-type: none"> <li>• Final Invoice is based on a reconciliation of all costs associated with the project not to exceed «Final_Amount»</li> <li>• Final Financial Report</li> <li>• Final Expenditure Report</li> <li>• Final Cumulative Grant Progress Report</li> <li>• Final Legislative Report (Reference page 3,5. b.)</li> </ul>	Life of the Grant	April 28, 2028

## **ATTACHMENT III**

See Section V APPENDIX (1) Reportable Financial Interests Page 34.

### **Attachment IV**

#### **Reportable Events for Research Involving Human Subjects**

Researchers must report to the Department within 48 hours any of the following reportable events, regardless of whether IRB has oversight over the research:

- Adverse events and adverse outcomes which in the opinion of the Principal Investigator are both unexpected and related and suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized.
- Any interim analysis or safety monitoring report indicating the frequency or magnitude of harms or benefits may be different than initially presented to the IRB.
- Any breach of confidentiality.
- Any change in FDA labeling or withdrawal from marketing of a drug, device, or biologic used in a research protocol.
- Any change to the protocol taken without prior IRB review to eliminate an apparent immediate hazard to a research subject.
- Any incarceration of a subject in a protocol not approved to enroll prisoners.
- Any event that requires prompt reporting to the sponsor.
- Any sponsor-imposed suspension for risk.
- Any protocol violation (meaning an accidental or unintentional change to the IRB approved protocol) that harmed subjects or others or that indicates subjects or others may be at increased risk of harm or has the potential to recur.
- Any unanticipated adverse device effect.
- Any non-compliance identified by Department of Health audit or monitoring.
- Any investigation by FDA or OHRP or other federal agency of research (not just including this study) by any researcher on the study.
- Any loss of license or hospital privileges by any researcher on the study.

## Attachment V Budget Summary and Narrative

See Section V APPENDIX (2) Budget Summary and Narrative Template Pages 35-40

### ATTACHMENT VI

#### AUDIT REQUIREMENTS FOR AWARDS OF STATE AND FEDERAL FINANCIAL ASSISTANCE

The administration of resources awarded by the Department of Health to recipient organization may be federal or state financial assistance as defined by 2 CFR § 200.40 and/or section 215.97, Florida Statutes, and may be subject to audits and/or monitoring by the Department of Health, as described in this section. For this agreement, the Department of Health has determined the following relationship exist:

1. \_\_\_\_\_ **Vendor/Contractor (215.97(z), F.S.) and (2 CFR § 200.23)**. Funds used for goods and services for the Department of Health's own use and creates a procurement relationship with Recipient which is not subject to single audit act compliance requirements for the Federal/State program as a result of this contract agreement.

A vendor/contractor agreement may also be used with an established Service Organization (SO) that is serving as a Third-Party Administrator and in this case, is subject to SSAE18 audit reporting requirements (see Part III. Other Audit Requirements).

2. \_\_\_\_\_ **Recipient/Subrecipient of state financial assistance (215.97(o)(y), F.S.)**. Funds may be expended only for allowable costs resulting from obligations incurred during the specified contract period. In addition, any balance of unobligated funds which has been advanced or paid must be refunded to the Department of Health as the state awarding agency. As well as funds paid in excess of the amount to which the recipient/subrecipient is entitled under the terms and conditions of the contract must be refunded to the Department of Health.
3. \_\_\_\_\_ **Recipient/Subrecipient of federal financial assistance (2 CFR § 200.40)** .Funds paid in excess of the amount to which the recipient/subrecipient is entitled under the terms and conditions of the contract must be refunded to the Department of Health as the Pass-Through state awarding agency. In addition, the recipient/subrecipient may not earn or keep any profit resulting from Federal financial assistance, unless explicitly authorized by the terms and conditions of the Federal award or this agreement.

**Note:** A vendor/contractor vs. recipient/subrecipient determination must conclude with the completion of **Exhibit 2** to identify the recipient's audit's relationship with the department.

### MONITORING

In addition to reviews of audits conducted in accordance with 2 CFR Part 200, Subpart F (formerly A-133) - Audit Requirements, and section 215.97, Florida Statutes (F.S.), as revised (see AUDITS below), monitoring procedures may include, but not be limited to, on-site visits by Department of Health staff, limited scope audits as defined by 2 CFR §200.425, or other procedures. By entering into this agreement, the recipient agrees to comply and cooperate with any monitoring procedures or processes deemed appropriate by the Department of Health. In the event the Department of Health determines that a limited scope audit of the recipient is appropriate, the recipient agrees to comply with any additional instructions provided by Department of Health staff to the recipient regarding such audit. The recipient further agrees

to comply and cooperate with any inspections, reviews, investigations, or audits deemed necessary by the Chief Financial Officer (CFO) or Auditor General.

## **AUDIT GUIDANCE**

### **PART I: FEDERALLY FUNDED**

This part is applicable if Recipient is a State or local government or a non-profit organization as defined in 2 CFR §200.90, §200.64, and §200.70.

1. If a recipient expends \$750,000 or more in Federal awards during its fiscal year, the recipient must have a single or program-specific audit conducted in accordance with the provisions of 2 CFR 200, Subpart F - Audit Requirements. **EXHIBIT 1** to this form lists the federal resources awarded through the Department of Health by this agreement. In determining the federal awards expended in its fiscal year, the recipient shall consider all sources of federal awards, including federal resources received from the Department of Health. The determination of amounts of federal awards expended should be in accordance with the guidelines established in 2 CFR §§200.502-503. An audit of the recipient conducted by the Auditor General in accordance with the provisions of 2 CFR §200.514 will meet the requirements of this Part.
2. In connection with the audit requirements addressed in Part I, paragraph 1, Recipient shall fulfill the requirements relative to auditee responsibilities as provided in 2 CFR §§ 200.508-.512.
3. If a recipient expends less than \$750,000 in Federal awards in its fiscal year, the recipient is not required to have an audit conducted in accordance with the provisions of 2 CFR 200, Subpart F - Audit Requirements. If the recipient expends less than \$750,000 in federal awards in its fiscal year and elects to have an audit conducted in accordance with the provisions of 2 CFR 200, Subpart F - Audit Requirements, the cost of the audit must be paid from non-federal resources (i.e., the cost of such an audit must be paid from recipient resources obtained from other than federal entities).

**Note:** Audits conducted in accordance with this part shall cover the entire organization for the organization's fiscal year. Compliance findings related to contracts with the Department of Health shall be based on the contract agreement's requirements, including any rules, regulations, or statutes referenced in the contract. The financial statements shall disclose whether the matching requirement was met for each applicable contract. All questioned costs and liabilities due to the Department of Health shall be fully disclosed in the audit report with reference to the Department of Health contract involved. If not otherwise disclosed as required by 2 CFR § 200.510, the schedule of expenditures of Federal awards shall identify expenditures by funding source and contract number for each contract with the Department of Health in effect during the audit period.

Financial reporting packages required under this part must be submitted within the earlier of 30 days after receipt of the audit report or 9 months after the end of Recipient's fiscal year end.

**PART II: STATE FUNDED**

This part is applicable if the recipient is a nonstate entity as defined by section 215.97(1)(n), Florida Statutes.

1. If a recipient expends a total amount of state financial assistance equal to or in excess of \$750,000 in any fiscal year of such recipient (for fiscal years ending June 30, 2017 or thereafter), recipient must have a State single or project-specific audit for such fiscal year in accordance with section 215.97, Florida Statutes; applicable rules of the Department of Financial Services; Chapter 10.550 (local governmental entities) or Chapter 10.650 (nonprofit and for-profit organizations), Rules of the Auditor General. **EXHIBIT I** to this contract indicates state financial assistance awarded through the Department of Health by this contract. In determining the state financial assistance expended in its fiscal year, recipient shall consider all sources of state financial assistance, including state financial assistance received from the Department of Health, other state agencies, and other nonstate entities. State financial assistance does not include Federal direct or pass-through awards and resources received by a nonstate entity for Federal program matching requirements.
2. In connection with the audit requirements addressed in Part II, paragraph 1, recipient shall ensure that the audit complies with the requirements of section 215.97(8), Florida Statutes. This includes submission of a financial reporting package as defined by section 215.97(2), Florida Statutes, and Chapter 10.550 (local governmental entities) or Chapter 10.650 (nonprofit and for-profit organizations), Rules of the Auditor General.
3. If a recipient expends less than \$750,000 in state financial assistance in its fiscal year (for fiscal years ending June 30, 2017 or thereafter), an audit conducted in accordance with the provisions of section 215.97, Florida Statutes, is not required. In the event that a recipient expends less than \$750,000 in state financial assistance in its fiscal year and elects to have an audit conducted in accordance with the provisions of section 215.97, Florida Statutes, the cost of the audit must be paid from the nonstate entity's resources (i.e., the cost of such an audit must be paid from recipient resources obtained from other than state funds).

**Note:** An audit conducted in accordance with this part shall cover the entire organization for the organization's fiscal year. Compliance findings related to contracts with the Department of Health shall be based on the contract's requirements, including any applicable rules, regulations, or statutes. The financial statements shall disclose whether the matching requirement was met for each applicable contract. All questioned costs and liabilities due to the Department of Health shall be fully disclosed in the audit report with reference to the Department of Health contract involved. If not otherwise disclosed as required by Florida Administrative Code Rule 69I-5.003, the schedule of expenditures of state financial assistance shall identify expenditures by contract number for each contract with the Department of Health in effect during the audit period.

Financial reporting packages required under this part must be submitted within 45 days after delivery of the audit report, but no later than nine months after recipient's fiscal year end for local governmental entities. Non-profit or for-profit organizations are required to be submitted within 45 days after delivery of the audit report, but no later than nine months after recipient's fiscal year end. Notwithstanding the applicability of this portion, the Department of Health retains all right and obligation to monitor and oversee the performance of this contract as outlined throughout this document and pursuant to law.

### **PART III: OTHER AUDIT REQUIREMENTS**

This part is applicable to a contractor, vendor and/or provider organization serving as a third-party administrator on behalf of FDOH programs and is classified or determined in the FDOH contract agreement to be a Service Organization (SO).

If the contracted entity is determined to be a SO, the entity must perform an attestation to the Service Organization Controls (SOC) and submit to FDOH a "Statement on Standards for Attestation Engagements (SSAE18) audit report within the assigned timeframe as agreed upon in the SO's contract agreement. The hired Auditor must make an evaluation consistent with the FDOH contract terms and conditions to determine which SSAE18 report types to perform for the required SOC types. Below are the options available for the SSAE18 reports.

#### **TYPES:**

1. **SOC 1** – A report on controls over financial reporting.
  - **Type 1 Report** - Report on the fairness of the presentation of management's description of the service organization's system and the suitability of the design of the controls to achieve the related control objectives included in the description as of a specified date.
  - **Type 2 Report** - Report on the fairness of the presentation of management's description of the service organization's system and the suitability of the design and **operating effectiveness** of the controls to achieve the related control objectives included in the description throughout a specified period. (**Auditor conducts testing**)
  
2. **SOC 2** – A report on controls that may be relevant to security, availability, processing Integrity, confidentiality, or privacy. These reports are intended to meet the needs of a broad range of users that need detailed information and assurance about the controls at a service organization relevant to security, availability, and processing integrity of the systems the service organization uses to process users' data and the confidentiality and privacy of the information processed by these systems. These reports can play an important role in:
  - Oversight of the organization
  - Vendor management programs
  - Internal corporate governance and risk management processes
  - Regulatory oversight
  - **Type 1 Report** - Report on the fairness of the presentation of management's description of the service organization's system and the suitability of the design of the controls to achieve the related control objectives included in the description as of a specified date.
  - **Type 2 Report** - Report on the fairness of the presentation of management's description of the service organization's system and the suitability of the design and **operating effectiveness** of the controls to achieve the related control objectives included in the description throughout a specified period. (**Auditor conducts testing**)

**PART IV: REPORT SUBMISSION**

1. Copies of single audit reporting packages for state financial assistance (CSFA) and federal financial assistance (CFDA) conducted in accordance with **2 CFR § 200.512 and section 215.97(2), Florida Statutes**, shall be submitted by or on behalf of recipient directly to:

- A. The Department of Health as follows:

[SingleAudits@flhealth.gov](mailto:SingleAudits@flhealth.gov)

Pursuant to 2 CFR § 200.521, and section 215.97(2), Florida Statutes, recipient shall submit an electronic copy of the reporting package and any management letter issued by the auditor to the Department of Health.

Audits must be submitted in accordance with the instructions set forth in Exhibit 3 hereto and accompanied by the "Single Audit Data Collection Form, Exhibit 4." Files which exceed electronic email capacity may be submitted on a CD or other electronic storage medium and mailed to:

**Florida Department of Health**  
Bureau of Finance & Accounting  
Attention: FCAM, Single Audit Review  
4052 Bald Cypress Way, Bin B01  
Tallahassee, FL 32399-1701.

- B. The Auditor General's Office as follows:

One electronic copy email by or on behalf of recipient directly to the Auditor General's Office at: [flaudgenlocalgovt@aud.state.fl.us](mailto:flaudgenlocalgovt@aud.state.fl.us).

One paper copy mail to:  
**Auditor General's Office**  
Claude Pepper Building, Room 401  
111 West Madison Street  
Tallahassee, Florida 32399-1450

2. In addition to item 1, electronic copies of reporting packages for federal financial assistance (CFDA) conducted in accordance with **2 CFR § 200.512** shall also be submitted by or on behalf of recipient directly to each of the following:

- A. The Federal Audit Clearinghouse (FAC), the Internet Data Entry System (IDES) is the place to submit the Federal single audit reporting package, including form SF-SAC, for Federal programs. Single audit submission is required under the Single Audit Act of 1984 (amended in 1996) and 2 CFR § 200.36 and § 200.512. The Federal Audit Clearinghouse requires electronic submissions as the only accepted method for report compliances. FAC's website address is: <https://harvester.census.gov/facweb/>

- B. When applicable, other Federal agencies and pass-through entities in accordance with 2 CFR §200.331 and § 200.517.

3. Copies of SSAE18 reports and supporting documents shall be submitted by or on behalf of SO/Third Party Administrator directly to the FDOH designated Contract Manager (CM) as outlined in each SO contract agreement.

**Note:** Any reports, management letter, or other information required to be submitted to the Department of Health pursuant to this contract shall be submitted timely in accordance with 2 CFR § 200.512 and Florida Statutes, Chapter 10.550 (local governmental entities) or Chapter 10.650 (nonprofit and for-profit organizations), Rules of the Auditor General, as applicable.

Recipients, when submitting financial reporting packages to the Department of Health for audits done in accordance with 2 CFR § 500.512 or Chapter 10.550 (local governmental entities) or Chapter 10.650 (nonprofit and for-profit organizations), Rules of the Auditor General, should indicate the date that the reporting package was delivered to recipient in correspondence accompanying the reporting package.

**PART V: RECORD RETENTION**

Recipient shall retain sufficient records demonstrating its compliance with the terms of this contract for a period of six years from the date the audit report is issued and shall allow the Department of Health or its designee, the CFO, or the Auditor General access to such records upon request. Recipient shall ensure that audit working papers are made available to the Department of Health, or its designee, CFO, or Auditor General upon request for a period of six years from the date the audit report is issued, unless extended in writing by the Department of Health.

**End of Text**

# EXHIBIT 1

Contract #: «Grant Number»

Federal Award Identification #: \_\_\_\_\_

**1. FEDERAL RESOURCES AWARDED TO THE SUBRECIPIENT PURSUANT TO THIS AGREEMENT CONSIST OF THE FOLLOWING:**

Federal Agency 1 \_\_\_\_\_ CFDA# \_\_\_\_\_ Title \_\_\_\_\_ \$ \_\_\_\_\_

Federal Agency 2 \_\_\_\_\_ CFDA# \_\_\_\_\_ Title \_\_\_\_\_ \$ \_\_\_\_\_

TOTAL FEDERAL AWARDS \$ \_\_\_\_\_

**COMPLIANCE REQUIREMENTS APPLICABLE TO THE FEDERAL RESOURCES AWARDED PURSUANT TO THIS AGREEMENT ARE AS FOLLOWS**

---

**2. STATE RESOURCES AWARDED TO THE RECIPIENT PURSUANT TO THIS AGREEMENT CONSIST OF THE FOLLOWING:**

State financial assistance subject to section 215.97, Florida Statutes: CSFA# \_\_\_\_\_

Title: \_\_\_\_\_ «Award Amount»

TOTAL STATE FINANCIAL ASSISTANCE AWARDED PURSUANT TO SECTION 215.97, FLORIDA STATUTES «Award Amount»

**COMPLIANCE REQUIREMENTS APPLICABLE TO STATE RESOURCES AWARDED PURSUANT TO THIS AGREEMENT ARE AS FOLLOWS:**

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.

Financial assistance not subject (exempt) to section 215.97, Florida Statutes or 2 CFR § 200.40: \$ \_\_\_\_\_

Financial assistance not subject (exempt) to section 215.97, Florida Statutes or 2 CFR § 200.40: \$ \_\_\_\_\_

---

**Matching and Maintenance of Effort \***

Matching resources for federal Agency(s):

Agency: \_\_\_\_\_ CFDA# \_\_\_\_\_ Title \_\_\_\_\_ \$ \_\_\_\_\_

Maintenance of Effort (MOE):

Agency: \_\_\_\_\_ CFDA# \_\_\_\_\_ Title \_\_\_\_\_ \$ \_\_\_\_\_

\*Matching Resources, MOE, and Financial Assistance not subject to section 215.97, Florida Statutes or 2 CFR § 200.306 amounts should not be included by recipient when computing the threshold for single audit requirements totals. However, these amounts could be included under notes in the financial audit or footnoted in the Schedule of Expenditures of Federal Awards and State Financial Assistance (SEFA). Matching, MOE, and Financial Assistance not subject to section. 215.97, Florida Statutes or 2 CFR § 200.306 is not considered State or Federal Assistance.

## EXHIBIT 2

### **PART I: AUDIT RELATIONSHIP DETERMINATION**

Recipients who receive state or federal resources may or may not be subject to the audit requirements of 2 CFR § 200.500, and/or section 215.97, Florida Statutes, recipients who are determined to be recipients or subrecipients of federal awards and/or state financial assistance may be subject to the audit requirements if the audit threshold requirements set forth in Part I and/or Part II of Exhibit 1 is met. Recipients who have been determined to be vendors are not subject to the audit requirements of 2 CFR § 200.501, and/or section 215.97, Florida Statutes. Recipients who are “higher education entities” as defined in Section 215.97(2)(h), Florida Statutes, and are recipients or subrecipients of state financial assistance, are also exempt from the audit requirements of Section 215.97(2)(a), Florida Statutes. Regardless of whether the audit requirements are met, recipients who have been determined to be recipients or subrecipients of Federal awards and/or state financial assistance must comply with applicable programmatic and fiscal compliance requirements.

**For the purpose of single audit compliance requirements, the Recipient has been determined to be:**

- \_\_\_\_\_ Vendor/Contractor not subject to 2 CFR § 200.501 and/or section 215.97, Florida Statutes
- \_\_\_\_\_ Recipient/subrecipient subject to 2 CFR § 200.501 and/or section 215.97, Florida Statutes
- \_\_\_\_\_ Exempt organization not subject to 2 CFR § 200.501; For Federal awards for-profit subrecipient organizations are exempt as specified in 2 CFR § 200.501(h).
- \_\_\_\_\_ Exempt organization not subject to section 215.97, Florida Statutes, for state financial assistance projects, public universities, community colleges, district school boards, branches of state (Florida) government, and charter schools are exempt. Exempt organizations must comply with all compliance requirements set forth within the contract.

**For other audit requirements, the Recipient has been determined to be:**

- \_\_\_\_\_ Service Organization (SO) subject to SSAE18 reporting requirements

**NOTE:** If a recipient is determined to be a recipient/subrecipient of federal and or state financial assistance and has been approved by the department to subcontract, it must comply with section 215.97(7), Florida Statutes, and Florida Administrative Code Rule 69I-.5006, [state financial assistance] and 2 CFR § 200.330 [federal awards].

### **PART II: FISCAL COMPLIANCE REQUIREMENTS**

**FEDERAL AWARDS OR STATE MATCHING FUNDS ON FEDERAL AWARDS.** Recipients who receive Federal awards, state maintenance of effort funds, or state matching funds on Federal awards and who are determined to be a subrecipient must comply with the following fiscal laws, rules and regulations:

1. 2 CFR Part 200- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards
2. Reference Guide for State Expenditures
3. Other fiscal requirements set forth in program laws, rules, and regulations

\*Some Federal programs may be exempted from compliance with the Cost Principles Circulars as noted in the 2 CFR § 200.401(5) (c).

\*\*For funding passed through U.S. Health and Human Services, 45 CFR Part 92; for funding passed through U.S. Department of Education, 34 CFR Part 80.

**STATE FINANCIAL ASSISTANCE.** Recipients who receive state financial assistance and who are determined to be a recipient/subrecipient must comply with the following fiscal laws, rules and regulations:

1. Section 215.97, Florida Statutes
2. Florida Administrative Code Chapter 69I-5,
3. State Projects Compliance Supplement
4. Reference Guide for State Expenditures
5. Other fiscal requirements set forth in program laws, rules and regulations

This document may be obtained online through the Florida Department of Health website under [Audit Guidance](#). \*Enumeration of laws, rules and regulations herein is not exhaustive or exclusive. Funding to recipients will be held to applicable legal requirements whether or not outlined herein.

## EXHIBIT 3

### INSTRUCTIONS FOR ELECTRONIC SUBMISSION OF SINGLE AUDIT REPORTS

**Part I:** Submission to FDOH

Single Audit reporting packages (“SARP”) must be submitted to the Department in an electronic format. This change will eliminate the need to submit multiple copies of the reporting package to the Contract Managers and various sections within the Department and will result in efficiencies and cost savings to recipient and the Department. Upon receipt, the SARP’s will be posted to a secure server and accessible to Department staff.

The electronic copy of the SARP should:

- Be in a Portable Document Format (PDF).
- Include the appropriate letterhead and signatures in the reports and management letters.

Be a single document. However, if the financial audit is issued separately from the Single Audit reports, the financial audit reporting package may be submitted as a single document and the Single Audit reports may be submitted as a single document. Documents which exceed 8 megabytes (MB) may be stored on a CD and mailed to: Bureau of Finance & Accounting, Attention: FCAM, Single Audit Review, 4052 Bald Cypress Way, Bin B01 (HAFA), Tallahassee, FL 32399-1701.

- Be an exact copy of the final, signed SARP provided by the Independent Audit firm.
- Not have security settings applied to the electronic file.
- Be named using the following convention: [fiscal year] [name of the audited entity exactly as stated within the audit report].pdf. For example, if the SARP is for the 2016-17 fiscal year for the City of Gainesville, the document should be entitled 2016 City of Gainesville.pdf.

Be accompanied by the attached “Single Audit Data Collection Form.” This document is necessary to ensure that communications related to SARP issues are directed to the appropriate individual(s) and that compliance with Single Audit requirements is properly captured. Questions regarding electronic submissions may be submitted via e-mail to [SingleAudits@flhealth.gov](mailto:SingleAudits@flhealth.gov) or by telephone to the Single Audit Review Section at (850) 245-4185.

**Part II:** Submission to Federal Audit Clearinghouse

Click [Here](#) for instructions and guidance to submit the completed SF-SAC report to the Federal Audit Clearinghouse website or click [Here](#) to access the SF-SAC Worksheet & Single Audit Component Checklist Form.

**Part III:** Submission to Florida Auditor General

Click [Here](#) for questions and other instructions for submitting Single SAC reports to the State of Florida, Auditor General’s Office

# EXHIBIT 4

## Single Audit Data Collection Form

### Part 1: GENERAL INFORMATION

**1. Fiscal period ending date for the Single Audit.**

Month	Day	Year
/	/	

**2. Auditee Identification Number**

a. Primary Employer Identification Number (EIN)

		--							
--	--	----	--	--	--	--	--	--	--

b. Are multiple EINs covered in this report  Yes  No

c. If "yes", complete No. 3.

**3. ADDITIONAL ENTITIES COVERED IN THIS REPORT**

Employer Identification #

Name of Entity

		--							
		--							
		--							
		--							

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**4. AUDITEE INFORMATION**

a. Auditee name:

Auditee Primary DUNS#:

b. Auditee address (number and street)

City

State Zip Code

c. Auditee contact

Name:

Title:

d. Auditee contact telephone

( ) -

e. Auditee contact FAX

( ) -

f. Auditee contact E-mail

**5. PRIMARY AUDITOR INFORMATION**

a. Primary auditor name:

b. Primary auditor address (number and street)

City

State Zip Code

c. Primary auditor contact

Name:

Title:

d. Primary auditor contact telephone

( ) -

e. Primary auditor E-mail

( ) -

f. Audit Firm License Number

**AUDITEE CERTIFICATION**

Date \_\_\_\_/\_\_\_\_/\_\_\_\_

Date Audit Received from Auditor: \_\_\_\_/\_\_\_\_/\_\_\_\_

Name of Certifying Official: \_\_\_\_\_  
(Please print clearly)

Title of Certifying Official: \_\_\_\_\_  
(Please print clearly)

Signature of Certifying Official: \_\_\_\_\_

# ANNUAL COMPENSATION REPORTING FORM



## Guidance

Most tax-exempt organizations are required to file an [annual return](#) with the Internal Revenue Service (IRS). Whether your organization meet this IRS filing requirement or is exempt from the [IRS 990](#) filing, the Florida Department of Health (Department) requires that this form be completed and submitted annually to support your organization's status with the executive compensation requirements.

Business Legal Name	Street Address Including City, State, and ZIP Code
Telephone	Department Contract #
Email	UEI or DUNS #
FEIN /Tax Id	Parent FEIN/Tax Id (if different)

Check here if 50% or more of your organization's revenues come from Federal, State or Other grant funds.

IRS Filing Status	Organization Types	Reported Status
<input type="checkbox"/> Not Exempt		
<input type="checkbox"/> Exempt From 990 <small>(Must complete all sections below)</small>		

	Top 5 Highest Paid Officers (Name/Title)	Total Amount Paid in Compensation and Benefits
1. Name /Title		
2. Name /Title		
3. Name /Title		
4. Name /Title		
5. Name /Title		

I attest that no salary and/or compensation benefits were allocated to Department program funds in excess of the Federal Executive Pay Scale threshold for Level II - \$197,300 ([Click Here to access the Pay Table](#)).

Signature: \_\_\_\_\_

Date of Signature: \_\_\_\_\_

**INSTRUCTIONS FOR COMPLETING THE FDOH EXECUTIVE COMPENSATION REPORTING FORM**

Most tax-exempt organizations are required to file an [annual return](#). Which form an organization must file with the Internal Revenue Service (IRS) [generally](#) depends on the organization’s financial activities. This FDOH form must be completed by all organizations (non-profits and pro-profits) who are awarded with state appropriation funds (federal/state) as a recipient of state financial assistance or as a sub-recipient of federal financial assistance. Please use the instructions below as a guide for completing each section of the FDOH form.

Business Legal Name	Street Address Including City, State, and ZIP Code
Telephone	FDOH Contract #
Email	UEI/DUNS #
FEIN/Tax Id	Parent FEIN/Tax Id (if different)
Business legal Name	Insert the exact name as shown on the IRS Tax Id registration certificate, Florida Sun Biz, MFMP registration or the organization name on the FDOH contract agreement. If the contract legal name is different from the registered legal name, please coordinate and contact your FDOH’s assigned Contract Manager.
Street Address	Input the mailing or physical address including zip code your organization uses for formal communication. This address may be different from the operating address/es where clients receive services
Telephone	Provide a direct ten (10) digits phone contact including extension number when applicable for follow up questions and inquiries.
FDOH Contract #	Insert all contract numbers for which your organization either received from FDOH as assets (equipment) and/or cash receipts during the reporting fiscal year.
Email	Please provide a secure email address for official business communications with FDOH.
UEI/DUNS #	Obtaining a DUNS number is a requirement for all grantees of federal funds. If your organization is funded with any federal funds (e.g. your contract agreement is labeled with an Assistance Listing Number (ALN, formerly CFDA), please input your DUNS or your assigned Unique Entity Identifier (UEI) number in this box.
FEIN/Tax Id	Please insert your exact nine (9) digits registered Tax Identification number. This should be the same as the Tax Id number on the FDOH contractual agreement. If different, please coordinate with your FDOH assigned Contract Manager.

## VI. APPENDIX II SUPPORTING DOCUMENTS

OMB No. 0925-0001 and 0925-0002 (Rev. 10/2021 Approved Through 09/30/2024)

### 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 USERNAME (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 <i>(if applicable)</i>	Completion Date MM/YYYY	FIELD OF STUDY
<input type="checkbox"/> <input type="checkbox"/>  <input type="checkbox"/> <input type="checkbox"/>  <input type="checkbox"/>			

**A. Personal Statement**

**B. Positions, Scientific Appointments, and Honors**

**C. Contributions to Science**

Please refer to the Biographical Sketch instructions on the [Biosketch Format Pages, Instructions and Samples](#), in order to complete sections A, B, C, and D of the Biographical Sketch.

## 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 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 Biomedical Research 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 FDA.

### **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.

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.

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.

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.

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

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.

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.

Institutional Animal Care and Use Committee Approval  
IACUC approval has been granted within the previous three years.  
IACUC approval is pending.

**Attachment VIII  
Florida Department of Health  
SUBCONTRACTING REQUEST FORM**

**Contractors/Providers/Grantees:** Complete this form and submit it to the assigned grant manager for review, along with the Recipient-Subrecipient and Contractor-Vendor Determination Checklist for State-Federal Funds, and a copy of the subcontract.

A. Subcontractor's legal name and address:

Legal Name: \_\_\_\_\_

Street Address: \_\_\_\_\_

City, State, Zip Code: \_\_\_\_\_

B. Complete Recipient-Subrecipient and Contractor-Vendor Determination Checklist (**Attachment VIII**) to determine subcontractor relationship:

Recipient/Subrecipient

Contractor/Vendor

C. Brief Description of the subcontract scope of work:

D. Amount of the subcontract: \$ \_\_\_\_\_

E. Percentage of subcontract allocated from primary agreement may not exceed 10% per the Funding Opportunity Announcement (FOA) (amount of subcontract ÷ amount of contract = percentage)

F. Does the subcontractor currently employ current or former DOH employees?

Yes

No

G. If yes to F, please provide the name(s) and the role(s).

Name:	Role:

H. Did any subcontractor staff participate in the Department's procurement of this contract?

Yes

No

**Attachment VIII  
Florida Department of Health  
SUBCONTRACTING REQUEST FORM**

I. If yes to H, please provide the name(s) and the role(s).

Name:	Role:

J. Does the subcontractor have any contracts, subcontracts, or grant agreements with DOH?

Yes                       No

K. If yes, please provide the contract/grant number(s) (Continue on a separate sheet if necessary).

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

L. Did the Grantee's subcontracting agreement include the requirement to comply with the prohibition of indoor smoking, pursuant to the Pro-Child Act of 1994? (Federal Funding Only - use N/A if contract does not consist of federal funds)

Yes                       No                       N/A

\*Not Applicable For Biomedical Research Grants

M. Did the Grantee's subcontracting agreement include the provisions for Audits, Records (including electronic storage media) and Records Retention?

Yes                       No

N. Did the Grantee's subcontracting agreement include the provision of independent capacity of contractor?

Yes                       No

O. Did the Grantee's subcontracting agreement adequately identify the financial assistance award information? (CSFA# and title, award year, name of awarding agency, award name/title - Subrecipient Only - use N/A if subcontractor was not determined as a subrecipient relationship)

Yes                       No                       N/A

P. Did the Grantee's subcontracting agreement advise the subrecipient of financial assistance of applicable laws, rules, regulations? (Subrecipient Only - use N/A if subcontractor was not determined as a subrecipient relationship)

Yes                       No                       N/A

Attachment VIII  
Florida Department of Health  
SUBCONTRACTING REQUEST FORM

Q. Did the Grantee's subcontracting agreement include the requirement that a financial and compliance audit be submitted to the Grantee per §215.97 (FL Single Audit Act), F.S. and/or OMB 2 CFR Part F? (Fed Single Audit Act - Subrecipient Only - use N/A if subcontractor was not determined as a subrecipient relationship)

Yes                       No                       N/A

R. Did the Grantee's subcontracting agreement include the requirement to submit the Annual Compensation Report including the most recent Internal Revenue Services (IRS) Form 990 by January 31 of each contract year? (Use N/A if subcontractor was not determined as a subrecipient relationship)

Yes                       No                       N/A

\*Not Applicable for Universities, Governmental Entities, and Vendors.

S. Did the Grantee's subcontracting agreement include the USDA WIC Services Assurance of Civil Rights Compliance requirement approved by the U.S. Department of Agriculture? (Use N/A if contract is unrelated to services or commodities being provided to WIC applicants or participants)

Yes                       No                       N/A

\*Not Applicable For Biomedical Research Grants

T. Did the Grantee's subcontracting agreement include background and drug screening requirements? (Attachment IX)

Yes                       No

U. Did the Grantee's subcontracting agreement include the Employment Eligibility Verification clause which requires subcontractors performing work or providing services pursuant to the contract use the E-Verify system to verify employment eligibility of all employees used by the subcontractor for the performance of service.

Yes                       No

Attachment VIII  
Florida Department of Health  
SUBCONTRACTING REQUEST FORM

**Attestation and Signature of Provider Representative/Authority**

“I, \_\_\_\_\_ certify that the provided  
(Printed/Typed Name of Grantee Representative)  
information is true and correct; the applicable provisions above have been incorporated in the  
subcontract agreement. I understand that the Department of Health reserves the right to review the  
subcontract agreement and additional documentation as needed.”

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Grant#: \_\_\_\_\_  
Title of Representative/Authority

**Department of Health Approval**

I, \_\_\_\_\_ have reviewed the information above and consulted with  
(Grant Manager)  
management. The request is:

Approved  Not Approved

Signature: \_\_\_\_\_ Date: \_\_\_\_\_ Grant #: \_\_\_\_\_  
Grant Manager

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Grant Manager's Supervisor

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Division Director

Attachment VIII  
Florida Department of Health  
SUBCONTRACTING REQUEST FORM

The purpose of the Subcontracting Guidelines is to assist grant managers and supervisors with the subcontracting process as well as provide instructions for completing the Subcontracting Request Form.

**BACKGROUND**

Per DOHP 250-14, subcontracting is defined as, “*When a DOH primary contractor makes a written agreement with another provider to perform part of the tasks or work covered in a DOH contract.*” A subcontractor’s IRS status, i.e. self-employed, professional affiliations or associations do not exclude providers from following this process. The DOH policy also prevents primary contractors from subcontracting 100% of the work. Primary contractors must remain responsible for all contract performance.

Division/Office/CHD contract managers may not approve any subcontractor not having an acceptable history with either DOH or the Department of Management Services. The Terms and Conditions must include language allowing subcontracting and the subcontract must adopt the Terms and Conditions.

**GUIDELINES**

The grantee must request approval to subcontract from the Department. Once the request is received, the grant manager must:

1. Determine whether or not the request is compliant with the Funding Opportunity Announcement and the Terms and Conditions. Thus, review the procurement and grant agreement to determine if subcontracting is allowed.
2. Send the provider the following forms for completion:
  - Subcontracting Request Form (Attachment VII);
  - Recipient-Sub-Recipient and Contractor-Vendor Determination Checklist. (Attachment VIII)
  - FDOH Contractual Services Background and Drug Screening Determination Checklist (Attachment IX);
  - Conflict of Interest Questionnaire (each individual involved in the selection of the subcontractor must complete this form) (Attachment X);

**NOTE:** When communicating with the grantee on the need for completing these forms, ensure to convey the due date for returning the forms for review.

3. Receive the completed forms from item #2 above and a copy of the proposed subcontract.
4. Review the completed forms and proposed subcontract. The Subcontracting Request form must be completed accurately, and in its entirety, which includes:

Attachment VIII  
Florida Department of Health  
SUBCONTRACTING REQUEST FORM

- Subcontractor Legal Name and Address as listed with the Florida Department of State, [SunBiz website](#), which should include the officers, directors, and principals to ensure no impropriety or conflicts of interest.
  - Verify the recipient/subrecipient/contractor vendor relationship was accurately determined.
  - Brief description of the subcontract work.
  - Amount of the grant. Determine the percentage of sub-contractual services that will be allocated from the primary agreement. Biomedical Research grants may not exceed 10%.
  - Intent to employ current and/or former DOH employees and if any participated in the procurement process. If so, obtain the names and positions of those employees. Determine if, and to what degree, any current or former employees were involved in the procurement process between DOH and the primary contractor.
  - Determine if the subcontractor has any other contracts or subcontracts with the Department.
  - Ensure the subcontract includes all applicable provisions from the Terms and Conditions. The following sections of the Department's Terms and Conditions must be included in the subcontract:
    1. 38. Backgrounding Screening Requirements and Drug Screening Requirements
    2. 20. Assignments and Sub-grants
    3. 7. Final Invoice
    4. 31. Use of Funds for Lobbying Prohibited
    5. 39. Public Entity Crime, Discriminatory Vendor, and Scrutinized Companies
    6. 22 and 24. Patents, Copyrights, and Royalties
    7. 21. Information Security and Confidentiality of Data, Files, and Records.
  - The Grantee must attest to the truthfulness of the form and that the required provisions are included in the subcontract.
  - **IMPORTANT:** Attest to reviewing the form and consulting with the supervisor and the division director. After the consultation, a determination must be made and marked on the form. The grant manager must notify the grantee in writing (email) of the final determination and explanation, if applicable.
5. Once subcontracts are approved and an executed copy is received, the grant manager is required to track all active subcontracts using the Subcontracting Tracker Form. Only active or current subcontractors should be listed on the form and updated as new agreements are executed. Biomedical Research will maintain a single tracker for all grants on SharePoint. Each Biomedical Research Grant Program grant manager will update this information regularly and no later than the 1<sup>st</sup> of each month and comply with any other request for updates by the Biomedical Research Grant Coordinator or member of the Department.