James and Esther King Biomedical Research Program

Funding Opportunity Announcement

FY 2014-2015

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James and Esther King Biomedical Research Program
Funding Opportunity: FY 2014-2015

NOTE: ONLY APPLICATIONS RECEIVED THROUGH THE ONLINE APPLICATION SYSTEM WILL BE ACCEPTED.

Applicants must register online at the program's website: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html to be able to submit an application. See section III for application preparation and submission instructions.

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

Sarah Hofmeister, Research Program Analyst, Public Health Research Unit
Phone: 850-245-4585 Email: Sarah.Hofmeister@flhealth.gov
Or
Robert Hood, Ph.D., Manager, Public Health Research Unit
Phone: 850-245-4585 Email: Robert.Hood@flhealth.gov

Florida Department of Health
Public Health Research Unit
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4052 Bald Cypress Way Bin A24
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I. OVERVIEW

1. Introduction

The James and Esther King Biomedical Research Program (hereafter referred to as the "Program"), is established in section 215.5602, *Florida Statutes* (s. 215.5602, *F.S.)*. 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.

2. Research Priorities

The Florida Biomedical Research Advisory Council has identified research priorities that define substantive areas of focus, and specific timeframes for evaluating success that will guide funding opportunities issued by the Department. All applications submitted in response to this funding opportunity must be responsive to one of the following eight research priorities. Because cancer and tobacco-related diseases have disparate impacts on Floridians, health equity and opportunity should be addressed in applications, including efforts to foster collaborations among institutions, researchers, and community practitioners. Researchers applying for funding as New Investigators, or with Team Science applications, or applications focused on Comparative Effectiveness Research will be given extra weight in the peer review process. Researchers conducting behavioral health research involving tobacco cessation and control are required to coordinate with Tobacco-Free Florida.

- Prevention and Treatment: Research with a focus on prevention and improved treatment or care delivery that **contributes to reduction in deaths** in lung cancer, breast cancer, prostate cancer, colon cancer, and melanoma.

- Health Disparities: Research that contributes to reductions in deaths due to lung cancer, breast cancer, prostate cancer, colon cancer, and melanoma resulting from **health disparities** due to race, ethnicity, or income.

- Screening: Improve screening accuracy, detection of high risk subgroups, and/or improved implementation of cancer screening program that results in an increase in early detection of cancer or preventable cancer.

- Tobacco Use: Reduction of tobacco use in children, adolescents, and adults.

- Obesity: Enhance the understanding of the relationship between obesity, healthy weight, and cancer.

- 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, CNS, reproductive, developmental).

In addition to the priorities listed above, applicants may apply for grants to support technology transfer and projects that support applications for Investigational New Drug or Investigational Device Exemption applications to the US Food and Drug Administration.

- 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 tobacco-related diseases; 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 eligible universities and research institutes in order 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 tobacco-related diseases.

        - Developing and/or improving assays useful in the prevention, diagnosis, and treatment for tobacco-related diseases.

- Developing new therapies and drugs for tobacco-related diseases.
- Developing methods, materials, models, or simulations necessary for translating research findings into standard practices for the prevention, diagnosis, and treatment for tobacco-related diseases.
- Eligible projects must satisfy all of 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 clean.
- 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.

- 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 US Food and Drug Administration as part of an application for marketing. The intent is to support promising new drug discovery and commercialization of new drugs.

3. Mechanisms of Support

The following types of grants are available to pursue the above eight research priorities.

Grant Mechanism	**Max Amount** (including direct and indirect costs)	**Max Duration**
Discovery Science	$1,500,000	3 years
Research Infrastructure	$1,500,000	3 years
Clinical Research	$2,000,000	5 years
Bridge	$100,000	6 months

Discovery Science

Discovery science means fundamental theoretical or experimental investigative research to advance knowledge without a specifically envisaged or immediately practical application. Directed to understanding the events related to the development or prevention of tobacco-related diseases at the molecular, cellular, and organismic levels, as well as the discovery and development of new drugs or therapies for tobacco-related diseases.

Maximum Award Amount: Up to $1,500,000.

Maximum Duration: Up to 3 Years.

Infrastructure

Eligible organizations may submit an infrastructure application in ***one*** of the following six areas: tissue banking, bioinformatics, genomics, diagnostic imaging, health disparities, and quality indicator systems, as described below. The Department is particularly interested in research involving quality indicator systems, when this is linked with other priorities, such as increasing the number of National Cancer Institute-designated cancer centers in Florida. 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 the state. Priority will be given to projects that demonstrate institutional collaboration in the pursuit of a research question or development of infrastructure.

Applications must describe:

- A plan for providing access to the funded infrastructure.
- A scientific advisory process involving researchers from at least two of the major cancer centers in Florida, and at least two regional cancer centers.
- A community advisory process that represents the perspective of participants in research, with particular focus on the perspectives of underserved and minority populations and communities that historically lack trust in research.

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

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

- **Tissue banking.** The solicitation is for infrastructure/resources to expand procurement of tissue samples for research in tobacco-related diseases; expand the intake, storage, and analysis of specimens; and expand the distribution of samples for research. The solicitation seeks applications for infrastructure/resources required to create sustainable programs that increase the number of samples from healthy persons and from under-represented groups, including but not limited to African-Americans and Hispanics in Florida. The expectation is that funded projects will result in the procurement of a substantial number of samples by the end of the grant period, as well as a sustainable program for ongoing collection of samples from healthy people and under-represented groups. In addition to expanding procurement through outreach and recruiting, funds may be used to expand existing infrastructure and software for intake, storage, and analysis, or expansion of an existing registry to different diseases. The expectation is that there will be a substantial improvement in the efficiency and effectiveness of registries, and that applications describe measurable targets and timeframes, and a process to evaluate improved outcomes from these improvements. Projects may include infrastructure and programs to improve dissemination and sharing of tissue samples and improve the research use of tissues 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 tobacco-related diseases. Projects may include improving algorithms, databases, and modeling of biological phenomena; purchase of equipment, 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 researchers at other universities and research institutes in the state, and describe measurable targets and timeframes for expanding access by researchers at other institutions in Florida on a sustainable basis, and 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 with an emphasis on cardiovascular and/or pulmonary diseases; the identification of markers brought on by unfavorable metabolic conditions and diseases, including obesity, diabetes and hyperlipidemia, that allow for the development of tissue-specific and identification of biomarkers and disease signaling pathways for tobacco-related diseases; the identification of a set of markers for metabolic dysfunction and improvements in ways of automating clinical imaging such as echocardiography.

- **Medical imaging.** The solicitation seeks to expand existing infrastructure that improves the quality, speed, and accuracy of medical imaging; creating systems and processes that measure the effectiveness of imaging technologies and their application in clinical practice; and projects that expand access to advanced imaging technologies by clinicians. Projects may include but are not limited to study of non-invasive measures of blood flow to improve treatment of cardiovascular disease; improvements in screening for lung disease and breast cancer; and research into the effectiveness of expanded use of imaging technologies on health outcomes and the development of protocols that align clinical use of imaging technologies with improvements in 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 researchers at other universities and research institutes in the state; describe measurable targets and timeframes for expanding access by researchers at other institutions in Florida on a sustainable basis, and 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, mass spectroscopy and automation. 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 researchers at other universities and research institutes in the state; describe measurable targets and timeframes for expanding access by researchers at other institutions in Florida on a sustainable basis; and describe a process to evaluate improved outcomes related to this infrastructure.

- **Health disparities.** In Florida there are significant differences in the morbidity and mortality of cancer, cardiovascular disease, stroke, and lung disease depending on location, race and ethnicity, and other social determinants of health. Priority will be given to projects that address areas of significant health disparities in the state, such as heart disease, breast cancer among African-American women and prostate cancer among African-Americans. Projects may include but are not limited to expanding access to core resources for researchers at minority-serving organizations; development of clinical guidelines and education programs to improve the quality and consistency of screening and clinical care; and the development of coordinating centers for research specific diseases involving significant health disparities. The expectation is that projects will include sustainable ongoing mechanisms to improve health disparities; and describe measurable targets and timeframes; and 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 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 researchers at other universities and research institutes in the state, and describe measurable targets and timeframes for expanding access by researchers at other institutions in Florida on a sustainable basis; and describe a process to evaluate improved outcomes related to this infrastructure.

Maximum Award Amount: Up to $1,500,000.

Maximum Duration: Up to 3 Years.

Clinical Research

Clinical research means research that gathers evidence of the benefits and harms of various treatment options for tobacco-related diseases, directly involves a particular person or group of people, or uses materials from humans, such as their behavior or samples of their tissue. Clinical research can involve observational trials, trials of new medications or medication combinations for tobacco-related diseases, behavioral health interventions, and healthcare delivery comparisons.

Maximum Award Amount: Up to $2,000,000.

Maximum Duration: Up to 5 years.

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. Allowable federal competitions include but are not limited to those conducted by the National Institutes of Health, 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 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 of 16th or better.

Maximum Award Amount: Up to $100,000.

Maximum Duration: Up to 6 Months.

Additional Information:

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

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.

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 Program 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.

All applications addressing tobacco use must include a letter of support from The Tobacco Free Florida Program (http://www.tobaccofreeflorida.com/). Please contact Brenda Roessler at Brenda.Roessler@flhealth.gov to request a letter of support.

Letter of Intent:

Submission of a Letter of Intent (LOI) is required to submit an application. The information it contains allows Department of Health staff to estimate the potential review workload and plan for the review.

By August 1, 2014, prospective applicants must submit a letter of intent that includes the following information:

- Name of Program (James and Esther King Biomedical Research Program or Bankhead-Coley Cancer Research Program)
- Name, address, and telephone number of the project director or principal investigator
- Names of other research personnel
- Lead Organization
- Descriptive title of proposed research

- Type of research priority
- Grant mechanism
- Collaborating institutions, if any

For collaborative and infrastructure applications, the lead organization is required to submit the LOI.

Applications will not be accepted if LOI is not received by the deadline of August 1, 2014.

The Letter of Intent should be sent to: Research@flhealth.gov

4. Highlights

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

- Application instructions will be available on or about July 28, 2014 at the program website:

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

- All applications must be submitted by the date indicated in I.5, Table 1 to be considered for funding during this competition. All submissions will be peer reviewed during the same time frame and awards will be announced and funded as indicated in I.5, Table 1.

- There is a defined question and answer timeframe as indicated in I.5, Table 1. All questions will be answered at **one** time on or around the date indicated in I.5, Table 1.

- When research involves human participants, grantees are required to obtain and maintain approval from an IRB accredited by the Association for Accreditation of Human Research Program Programs (AAHRPP), or an IRB acceptable to the Department, within 60 days of notice of award. Grantees should be prepared to start the regulatory review process at their institution immediately upon being notified of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department.

- The Program will pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. The **maximum annual base salary** used in calculating these payments must not exceed the Executive Level 2 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.

- Applicants are encouraged to check the Program website regularly throughout the application, peer review, and award processes for Program announcements, amendments, and answers to programmatic questions.

5. Schedule of Important Dates

Table 1. Schedule of Important Dates		
ACTIVITY	**DATES**	**IMPORTANT INFORMATION**
Funding opportunity announced	On or around July 16, 2014	Located on the program website at: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html
Letter of Intent due (required)	Letter of Intent must be submitted by August 1, 2014 5:00 p.m. EST	Letter of Intent must be submitted to research@flhealth.gov
Online application system opens	On or around August 1, 2014	Create user account and submit application: https://biomed.fluidreview.com/
Written questions accepted	Questions may be submitted any time until 5:00 p.m. EST August 8, 2014	E-mail questions to: research@flhealth.gov
Answers posted to written questions	One time on or around August 15, 2014	Questions and answers will be published on the program website
Applications due	Applications must be submitted before 5:00 p.m. EST August 22, 2014	Applications must be submitted through https://biomed.researchexcellence.net/
Awards announced	On or around December 12, 2014	Award letters and Terms & Conditions will be E-mailed to the Administrative Official and the Principal Investigator. Terms and Conditions must be executed and returned no later than January 1, 2015

Institutional reviews due (if applicable)	Immediately after award notification, grantees should submit application(s) for all institutional authorizations including, but not limited to the Institutional Animal Core, Use Committee (IACUC) and 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 as the application project title and must be signed by the Review Board chairperson or organizational representative.	Visit the program website for guidance on regulatory review procedures for biomedical grant program research. Grantees should be prepared to start the regulatory review process at their institutions immediately upon being notified of award.
Grants begin	February 1, 2015	Contingent on verification of all eligibility requirements and regulatory approvals.
Proposal evaluation summaries available to applicants online	On or before April 1, 2015	The evaluation report will be available to applicants at: https://biomed.researchexcellence.net/ Applicants will be notified when the evaluation report is available.

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

II. ELIGIBILITY AND APPLICATION REQUIREMENTS

1. Tobacco-Relatedness

All applicants must clearly demonstrate how the proposed project is relevant to tobacco-related cancer, cardiovascular disease, stroke, and pulmonary disease. Biomedical and biotechnological research proposals must address the etiology, pathogenesis, prevention, diagnosis, treatment, and/or cure of diseases related to tobacco use such as cancer, cardiovascular disease, stroke, and pulmonary disease. Social scientific and behavioral proposals must address the development, implementation, and/or evaluation of existing or novel approaches to tobacco control, tobacco education, prevention of tobacco use, or nicotine addiction; and/or address the health needs of current and/or former tobacco users. Proposals that do not or cannot demonstrate the relatedness between tobacco use and the proposed project will not be funded.

2. Eligibility Requirements

A. Eligible Applicants

The applicant must be an eligible institution (see the definitions provided in II.7, and all awards will be made to institutions, not individuals.

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

According to s. 215.5602(5)(a) and s. 381.922(3)(a), *F.S*., applications for biomedical research funding may be submitted from any university or established research institute in the state. Eligible institutions include state universities, nonpublic institutions, and established research institutes (see the definitions provided in II.7).

The applicant organization, in accordance with its own policies and procedures, should designate the Principal Investigator. The Principal Investigator must supervise the project directly and in person. Grant applications from Principal Investigators failing to meet all applicable eligibility requirements will be rejected. The Principal Investigator is the individual designated by the applicant organization legally responsible to direct the grant project. The 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.

To be eligible as a Principal Investigator at an eligible institution**,** the individual must be a full-time faculty member by the time the application is submitted. Temporary faculty members, even though full-time, are not eligible to apply. See Full-time Faculty and Full-time Equivalent definitions in II.7.

An applicant 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.

If the principal Investigator moves to another eligible institution during the award period, the award shall remain with the original awardee institution, and a new principal investigator from that institution must be approved by the Department.

B. Guidelines for Florida Biomedical Research Advisory Council Member Participation

The Florida Biomedical Research Advisory Council (Council) has statutory conflict of interest obligations regarding the participation of its members in Bankhead-Coley Cancer Research Program and James and Esther King Biomedical Research Program grants and grant applications.

Council members shall not:

- Receive any form of financial compensation from a James & Esther King grant award.
- Participate in any named role on a proposed James & Esther King grant project in this Call.
- Advise applicants regarding the preparation of a specific James & Esther King grant application.
- Answer any programmatic questions (eligibility, content of the Funding Oppotunity, competition procedures, etc.).
- Violate any provision of Chapter 112, Part III, F.S.

Council 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 Advisory Council members, refer to the program website.

C. Duplicate Applications and Overlap Limits

The Principal Investigator may:

- Submit two completely different projects at the same time to the two Programs (Bankhead-Coley and King).

- Submit a single re-submission of the same or very similar project, regardless of change in application title for both Bankhead-Coley and James & Esther King Programs.

The Principal Investigator shall not:

- Submit an application for the same research project for which he or she was previously funded as a Bankhead-Coley or James & Esther King Grant recipient. The aims and experiments in the new proposal must be significantly different from any previous grants.

- Submit duplicate projects or projects with significant scientific or financial overlap to different mechanisms within the James and Esther King Biomedical Research Program.

- Submit the same project/research to the James and Esther King Program that is also being submitted by another investigator regardless of the grant mechanism.

- Submit duplicate projects or projects with significant scientific or financial overlap to both the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program during the same competition year.

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

3. Required Grant Application Components

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

Proposals exceeding the page limits where specified are subject to truncation to the page limit or may be disqualified without review. All required application forms are available for download within the online application in the Research Management System.

Table 2. Grant Application Components and Page Limits

Section	Category	Page Limit	Comment
General Project Information:			
A*	General Project Information	2	Required. Identifies general project information, the applicant organization, and the Principal Investigator.
B*	General Audience Abstract	1500 characters	Required. Explains the proposed project in lay terms, including its relationship to the goals of the Program.

Table 2. Grant Application Components and Page Limits			
Section	**Category**	**Page Limit**	**Comment**
C*	Scientific Abstract	2000 characters	Required. This is the scientific description of the project.
D*	Tobacco-Relatedness	3000 characters	Required. Provides a clear explanation of how the project is related to tobacco use or diseases related to tobacco use.
E*	Type of Research Priority and Grant Mechanism	1500 characters	Required. Identifies one of the eight research priorities the proposed project plans to address and which type of grant mechanism.
F*	Health Impact	1500 characters	Applications, except those for discovery science, 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 tobacco-related diseases. 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, and improve disease prevention through improvements in health literacy and changes in behavior within a certain amount of time. Do not 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 as a health impact that may result from the research.
G*	Key Personnel	1	Required. Identifies all key personnel.

Table 2. Grant Application Components and Page Limits			
Section	**Category**	**Page Limit**	**Comment**
Main Application Body:			
H**	Table of Contents	1	Required.
I**	Resources	2	Required.
J**	Introduction to Resubmitted Application	3	Required (if applicable).
K**	Research/Project Plan	12	Required.
L**	Literature Cited	3	Required.
M**	Human Subjects	No limit	Required (if applicable).
N**	Vertebrate Animals	No limit	Required (if applicable).
O**	Consultants	4	Required (if applicable).
P**	Survey Instruments	No limit	Optional.
Budget:			
Q	Budget	6	Required. The budget must explain the planned spending. See appendix for template.
Other Documents:			
R	Biographical Sketches	4 per person	Required for the Principal Investigator and any other key personnel.
S	Research/Project Milestone Chart	2	Required. Provides a high-level overview of the project schedule.
T	Other Support	No Limit	Required. All other active and pending awards for the Principal Investigator.
U	Cover/Certification Page – Signed	1	Required. Principal Investigator will be able to electronically sign application.

Table 2. Grant Application Components and Page Limits			
Section	**Category**	**Page Limit**	**Comment**
* (Sections A-G) Submitted materials are subject to the provisions of Art. I, Sec. 24, *Florida Constitution* and Chapter 119, *F.S.,* Florida's public records laws. These laws grant anyone the right to inspect any public record. Applicants are discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. ** (Sections H-P) 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 Main Application Body. 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 Program, as well as disallowed costs.

A. Allowed Direct Costs

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

- Salaries
- Fringe benefits
- Supplies
- Equipment
- Lab Services
- 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*)
- Consultant costs
- Patient-care costs
- Animal-care costs
- IRB or IACUC fees (if the project involves human participants)
- Consortium or contractual costs
- Fees to obtain data from the Florida Cancer Registry Data System and Florida Office of Vital Statistics

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

- the services, functions, or activities are directly necessary for this grant,

and
- these administrative costs have not been included in the calculation of the indirect costs.

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

Maximum Annual Base Salary Calculations:

The Program will pay a proportional percentage of the base salary (based on effort) of any personnel named on the application for this grant. The maximum annual base salary used in calculating these payments must not exceed the Executive Level 2 annual salary rate of the Federal Executive Pay Scale that is in effect as of the application submission date. See II.7, Definitions, for more information about the Federal Executive Pay Scale. This salary cap excludes fringe benefits, facilities, and administrative (F&A) expenses, and also excludes any income that an individual may be permitted to earn outside of the duties to the applicant organization. This provision is consistent with the NIH salary limitations on grants, cooperative agreements, and contracts.

Work Must Occur in Florida:

All activities funded through this competition must occur in Florida. All work (effort) must occur and 100% of funds must be spent in Florida at the applicant organization and any collaborating entities.

B. Allowed Indirect Costs

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 15% of the direct costs requested. Indirect costs are those costs that are incurred for the joint or common benefit of several separate organizational or financial components (cost centers) of an organization, which specifically or readily cannot be identified to a particular cost center, project, or program.

C. Disallowed Costs

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

- Florida Department of Health personnel
- 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, accepting applications, and is responsible for answering all applicant questions. Applicants and persons acting on their behalf may contact the Department in writing via E-mail as indicated below regarding programmatic issues. Applicants who attempt to contact Biomedical Research Advisory Council members regarding this Call for Grant Applications may have their applications disqualified.

To ensure equal access by all applicants to questions and answers, all programmatic questions must be submitted in writing via E-mail to research@flhealth.gov.

Answers to questions will be available on program website. Answers to Frequently Asked Questions will be posted to the website. Answers to submitted questions will be posted one time on the website, according to the schedule in I.5, Table 1.

B. Technical Questions About the Online Application

Direct all questions about the online application process and related issues (e.g. username and password problems) to support@fluidreview.com

If you experience technical difficulties during the final hours of the competition, please contact technical support at support@fluidreview.com immediately for assistance. 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, *F.S.,* 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 Main Application Body. 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

Business entity: Per s. 606.03(1), *F.S.,* 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 Principal Investigator in the scientific development or execution of the project. These individuals typically devote a specific percent of effort to the project and are identified as key personnel. The collaborator may be employed by, or affiliated with, either the Grantee institution or an institution participating in the project under a consortium or contractual agreement.

Commercialization: The process of developing markets and producing and delivering products or services for sale (whether by the originating party or by others). As used by the Program, commercialization includes both government and non-government markets.

Consortium or Contractual Agreement: An agreement whereby a project is carried out by the Grantee and one or more other organizations that are separate legal entities. In this arrangement, the Grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium's Principal Investigator and a breakdown of costs by category, such as personnel, supplies, and other allowable expenses, including indirect costs.

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

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

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

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

Eligible Institution: Any public university, non-public institution, or established research institute (see specific definitions of each) 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, *F.S.*, 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. For purposes of this competition, federal government and non-profit medical and surgical hospitals including Veteran's Administration hospitals are not considered eligible research institutes.

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 2: 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 2 pay scale, visit the website of the U.S. Office of Personnel Management at http://www.opm.gov/oca/ and search for executive schedule.

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

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

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

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

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

Key Personnel: Key personnel are defined as, and should be limited to, individuals who contribute to the scientific development or execution of the project in a substantive way, whether or not salaries are requested.

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

Overlap, Commitment: Commitment overlap occurs when any project staff has time commitments exceeding 100%. This is the case whether or not the grant includes salary support for the effort. While information on other support is only requested for the Principal Investigator, no individual on the project may have combined commitments in excess of 100%.

Overlap, Financial: Financial overlap occurs when duplicate or equivalent budget items (e.g., equipment, salary) are requested in an application but are already funded or provided for by another source.

Overlap, Scientific: Scientific overlap occurs when: (1) substantially the same research is funded by two or more different funding sources, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more awards, regardless of the funding source.

Principal Investigator: The one individual designated by the applicant organization to direct the project to be supported by the grant. The Principal Investigator is responsible and accountable to applicant organization officials for the proper conduct of the project. The Principal Investigator must supervise the project directly and in person.

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

Translational research: Research that fosters the multidirectional integration of basic research, patient-oriented research, and population-based research, with the aim of enhancing the adoption of best practices in the community and improving the health of the public. T1 research expedites the movement between basic research and patient-oriented research that leads to new or improved scientific understanding or standards of care. T2 research facilitates the movement between patient-oriented research and population-based research that leads to better patient outcomes, the implementation of best practices, and improved health status in communities. T3 research promotes interaction between laboratory-based research and population-based research to stimulate a robust scientific understanding of human health and disease. Examples of translational research include measures or mechanisms to improve access to clinical trial information for patients and/or physicians, and interventions to increase patient participation in clinical trials that move research from laboratory to clinical application.

III. INSTRUCTIONS FOR APPLICATION PREPARATION AND SUBMISSION

1. General Instructions for Application Submission

Applicants must register online at the Program's website: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html to be able to submit an application.

All applications must be prepared and submitted online through the Research Management System, accessible from the Program's website. 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 Research Management System (https://biomed.researchexcellence.net/) will be available to accept applications for this Funding Opportunity on or about August 1, 2014.

To complete the online application process:

1. Applicants must register to access the online application and forms. Register for an online application at https://biomed.fluidreview.com/ and complete the brief project profile. Information entered into the Registration fields will carry forward to the application and can be modified within the application if needed. Registration will be acknowledged with an E-mail message containing login instructions and a username and password.

2. Complete the online application form. Deviations may be grounds for the Program to reject the entire application. Special formatting, scientific notation, pictures, and objects may be included in these documents. However, within the online application form fields such as the Project Title, General Audience Abstract and the Scientific Abstract, use only conventional alphanumeric letters and numbers (i.e., ASCII text) with no drawings, special characters, or symbols.

3. If an application is accidentally submitted, contact program staff for assistance.

4. An application cannot be changed after the submission due date. 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. Place the Principal Investigator's name (last, first) in the designated space on each page. 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. Observe the character and page number limitations. A summary of these limitations is given in I.5, Table 1. Character limits include spaces. Applicants are encouraged to confirm compliance with this requirement by printing the full application before submission. Applications that exceed the page limits are subject to truncation to the page limit or may be disqualified without review. All applications must be self-contained within specified page limits. Unless otherwise specified in this document, Internet Web site addresses (URL's) 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 I.5, Table 1. Use the table to ensure that a complete application is submitted. Uploaded files should be titled by the categories listed in the table and page numbered within the form. Appended material may not be used to circumvent the page limits for individual sections of the application**.**

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 of I.5. The Department does not allow submitted application files or data to be replaced or changed after the submission deadline. This decision will help ensure no applicants receive an unfair advantage. Before submitting your application, please check it for completeness, accuracy, quality, and readability. This should include verifying that all graphic elements, including tables, charts, and images, converted properly when saving the original documents in PDF format as required.

2. Evaluation of Applications

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

A. Administrative Review

Application materials not received according to the date, time, and location specified in Table 1 of I.5 will be disqualified.

Each application submitted by the deadline indicated in Table 1 of I.5 will receive an administrative review verifying mandatory eligibility requirements and the completeness of the application. 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 the State. At its option, the Program may correct minor irregularities, but is under no obligation to do so.

B. Peer Review

Department peer reviewers will assess the overall impact of all qualified/eligible applications, and at the discretion of the Department may assess some ineligible/disqualified applications. Peer review panels will be comprised of reviewers with expertise in the substance and methodology of the proposed project. Individual reviewers will review and rate applications, including assessing tobacco-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 National Institutes of Health, 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:

Reviewer concerns regarding protection of human and/or animal subjects will be considered.

Separately, peer reviewers will rate the relationship of the project to the advancement toward prevention, diagnosis, treatment, and/or cure of diseases related to tobacco use. Peer reviewers will be asked the question "Has the applicant made a compelling case for a strong tobacco relationship?" Tobacco-relatedness will be rated using a five-point scale: (1) Definitely, (2) Yes, minor reservations, (3) Somewhat, (4) Minimally, and (5) Not at all. The tobacco-relatedness ratings of all reviewers will be averaged to determine the overall score for tobacco-relatedness.

Peer reviewers will also identify any concerns regarding the proposed budget or apparent scientific or budgetary overlap with active or pending support.

C. Programmatic Review

The Department and the Florida Biomedical Research Advisory Council will consider the peer review scores/rankings and scores regarding tobacco-relatedness in a manner that eliminates or appropriately manages any conflicts of interest. Other programmatic interests, such as the availability of funds, and Program goals and preferences, will be used to form a funding recommendation to the State Surgeon General.

D. Evaluation Reports

For all eligible and qualified applications, evaluation report will be available at https://biomed.researchexcellence.net/ on or before April 1, 2015.

3. Notification of Funding Decision

The applicant organization and Principal Investigator will receive written notification of the funding decisions as indicated in in Table 1 in I.5.

4. Requests for Re-Consideration

All funding decisions of the State Surgeon General are final.

5. Grantee Requirements

A. Terms and Conditions

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

B. Grantee Reporting Requirements

If the applicant's proposal is funded, the Grantee must respond to Department requests for information for a period of five (5) years after the end of the grant period, including any no cost extensions. The requested information may include, but is not limited to long-term outcomes based on the funded project, including the value of additional grant awards for tobacco-related research, a list of tobacco-related presentations, a list of tobacco-related 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.

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

V. APPENDIX

1. Reportable Financial Interests

**Sample. Subject to revisions.

Florida Department of Health Financial Conflict of Interest in Research

Principal Investigator:

Title of project:

Grant number:

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

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

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

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

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

☐ The grantee has no financial interests requiring disclosure

Signed

Dated

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

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

2. Budget Template Form

BIOMEDICAL RESEARCH PROGRAM

BUDGET BREAKDOWN BY CATEGORY

INSTITUTION: _____ **FDOH GRANT #**_____

PRINCIPAL INVESTIGATOR (NAME):_____

GRANT PERIOD FROM: _____ **TO:** _____

CATEGORY	BUDGET YEAR 1 PERIOD 12/1/13 – 12/31/14	BUDGET YEAR 2 PERIOD 1/1/15 – 11/30/15				TOTAL BUDGET FOR GRANT PERIOD
						0.00
a. Personnel						0.00
b. Fringe Benefits						0.00
c. Travel						0.00
d. Equipment						0.00
e. Supplies						0.00
f. Contractual						0.00
g. Patient Care Costs						0.00
h. Other						0.00
i. SUB-TOTAL						0.00
j. Indirect						0.00
k. TOTAL						

Signature:

Name:

Title:

Date:

**Sample. Subject to revisions.

3. Budget Narrative Form

Justify each entry by describing how it is related to the project. Where appropriate, include details that show how the estimated cost was calculated. Use additional sheets as necessary.

Name	Role on Project	Type of Appt. (months)	% Effort on Project	Base Salary	Fringe	Project Salary (% effort x base salary)	Project Fringe (% effort x fringe)	Total
				TOTAL PERSONNEL:				

Personnel:

Consultants:

Consortium /Contractual:

Equipment:

Supplies:

Travel:

Patient Care:

Other Expenses:

**Sample. Subject to revisions.

4. Terms and Conditions Template

Sample. Subject to revisions

Florida Department of Health
James and Esther King Biomedical Research Program
and
Bankhead-Coley Cancer Research Program

Terms and Conditions

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

The following Call for Applications ("Call"), including any Call amendments, and the application ("application") submitted by the Grantee in response thereto, are hereby incorporated by reference as part of this binding agreement:

- James & Esther King Biomedical Research Program Call for Grant Applications: Grant for Diseases Related to Tobacco Use, Fiscal Year (To Be Determined), Fiscal Year (TBD)and Fiscal Year (TBD) (TBD), effective on or before (TBD) – (TBD).
- Bankhead-Coley Cancer Research Program Call for Grant Applications: Grant for Diseases Related to Tobacco Use, Fiscal Year (To Be Determined), Fiscal Year (TBD)and Fiscal Year (TBD) (TBD), effective on or before (TBD) – (TBD).
- Grantee must comply with the provisions outlined in those documents, all applicable federal and State of Florida laws, rules, and regulations, and with the following terms and conditions to receive and maintain grant awards.

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

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

   a. Grantee shall update the Department, in writing, every 30 days after the original start date of the grant period as shown in Attachment I. Failure to keep the Department informed shall result in financial consequences of ten percent per invoice or grant termination.

   b. If the project has not started 90 days after the original start date of the grant period, the Department shall impose financial consequences of ten percent per invoice or grant termination.

   c. If the project requires commencement before IRB approval, the Grantee may seek authority to begin a portion of the project pending IRB approval.

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

   a. The Grantee shall prepare and submit to the Department throughout the grant period; financial reports, narrative progress reports that include a description of the impact of the research on health outcomes, and the deliverables as outlined in Attachment II. Reports must be prepared in the format specified by the Department.

   b. The Grantee agrees to make all reasonable efforts to assist the Department in gathering data required for reporting to the Florida Legislature and Governor pursuant to sections 215.5602(10) and 381.922(4), Florida Statutes, and other laws, as applicable, both during and after the grant period. Upon request, Grantee 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, published reports, databases, additional grants and monies received, patents, invention disclosures, and copyrights.

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

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

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

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

5. **Scope of Work and Project Adjustments:**

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

   b. Any type of project adjustment from that which was proposed in the application, including changes in the designs, aims, or research plans, and any changes requiring IRB and/or IACUC approval, and any change that may result in a conflict of interest must be submitted in writing and is subject

to Department approval prior to the change taking place. Failure to obtain prior approval shall result in financial consequences of ten percent per invoice.

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

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

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

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

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

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

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

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

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

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

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

   b. All equipment purchased with grant funds is the property of the eligible institution, and is subject to Chapter 273, Florida Statutes, dealing with state-owned tangible personal property and the disposition thereof. For research institutions not covered under Title XLVIII, Florida Statutes, equipment no longer deemed to be useful shall remain state property and must be transferred or donated to a state agency or public university for redistribution or disposition.

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

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

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

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

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

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

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

11. **Return of Funds:** This grant is a fixed payment grant, not a fixed price grant. The Grantee shall 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. In the event that the Grantee or its independent auditor discovers that overpayment has been made, the Grantee shall repay said overpayment within 40 calendar days of discovery without prior notification from the Department. In the event that the Department first discovers an overpayment has been made, the Department will notify the Grantee of such a finding. Should repayment not be made in a timely manner, the Department may withhold the amount of the overpayment from any future payments under this or any other agreement. This provision shall not be a limitation on any remedies at law or equity available to the Department.

12. **Monitoring:** The Grantee shall permit persons duly authorized by the Department to inspect any records, papers, documents, facilities, and/or goods and services of the Grantee that are relevant to this grant, and/or interview any clients, subcontractors, and employees of the Grantee to assure the Department of satisfactory performance of the terms and conditions of this grant. Monitoring may take place at any time during the grant period or records retention period with reasonable advance notice during normal business hours. Following such evaluation, the Department may deliver to the Grantee a written report of its findings and may include written recommendations with regard to the Grantee's performance of the terms and conditions of this grant. The Grantee will correct all noted deficiencies identified by the Department within the specified period of time set forth in the

recommendations. The Grantee's failure to correct noted deficiencies may, at the sole and exclusive discretion of the Department, result in any one or a combination of the following: (1) the Grantee being deemed in breach or default of this agreement; (2) the withholding of payments to the Grantee by the Department under this or any other agreement; (3) the termination of this grant.

13. **Access to Records:** The Grantee shall assure that records shall 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 shall 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.

14. **Retention of Records:** The Grantee shall 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 (6) 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 (6) years, the records shall be retained until resolution of the audit findings or litigation, which may be based on the terms of this grant. Upon completion or termination of the grant and at the request of the Department, the Grantee will cooperate with the Department to facilitate the duplication and transfer of any said records or documents during the required retention period as specified.

15. **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/or 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. The Grantee is responsible for monitoring changes in other support for project key personnel to avoid financial overlap. The 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, the Grantee must immediately notify the Department and resolve the overlap by: a) modifying at least one of the awards to eliminate the overlap or b) relinquishing one of the awards. Updated information on other support may be requested by and shall be provided to the Department at any time during the grant period.

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

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

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

19. **Publications, Presentations or Printing of Reports:** Any publications, presentations, printed reports, or resulting research findings related to this grant shall acknowledge the appropriate funding source: Florida Department of Health, James & Esther King Biomedical Research Program, Florida Department of Health, Bankhead-Coley Cancer Research Program. Grantee shall notify the Department of all publications, presentations, printed reports, and resulting research findings created for this project both during the grant period and for a period of six years after the grant period.

20. **Public Access:**

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

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

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

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

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

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

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

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

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

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

22. Policy Regarding Scientific Misconduct: The following provisions shall apply to ensure research integrity and manage scientific misconduct.

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

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

23. Human Subjects: The following provisions shall apply if the project involves human subjects:

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

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

c. Grantees are required to obtain and maintain approval from an IRB accredited by the Association for Accreditation of Human Research Program Programs (AAHRPP), or an IRB acceptable to the Department, within 60 days of notice of award. Grantees are required to follow Department policies for reporting unanticipated problems and non-compliance involving the research to the Department.

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

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

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

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

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

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

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

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

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

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

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

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

28. **Insurance:** The Grantee shall 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, F.S., the Grantee accepts full responsibility for identifying and determining the type(s) and extent of liability insurance necessary to provide reasonable financial protections for the Grantee and the clients to be served under this grant, if any. Upon execution of this grant, upon request the Grantee shall 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.

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

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

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

        ii. Reasonable; and

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

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

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

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

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

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

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

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

    Nothing in this grant agreement is intended to serve as a waiver of sovereign immunity, nor shall 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.

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

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

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

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

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

33. **Contact:**

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

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

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

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

GRANTEE:

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

FLORIDA DEPARTMENT OF HEALTH:

Signature of Authorized Official	Date
Typed or Printed Name of Authorized Official	Florida Department of Health

Attachment I

Florida Biomedical Research Programs **Terms and Conditions**	
Program:	
Program CSFA #:	
Grant ID:	
Type of Grant:	
Institution:	
Principal Investigator:	
Project Title:	
Grant Period:	
Total Grant Award:	
Year One Amount:	
Year Two Amount:	

Florida Biomedical Research Programs

Terms and Conditions

Schedule of Deliverables and Payments		
Deliverable	**Period Covered**	**Due Dates**
• Completed Financial Information Form • 1st Quarter Progress Summary • 1st Quarter Financial Report • Invoice for $		
• Continuation Request • New Budget Review		
• 2nd Quarter Progress Summary • 2nd Quarter Financial Report • Invoice for $		
• 3rd Quarter Progress Summary • 3rd Quarter Financial Report • Invoice for $		
• 4th Quarter Progress Summary • 4th Quarter Financial Report • Invoice for $		
• Annual Narrative Progress Report • Research Milestone Chart		
YEAR TWO		
• 1st Quarter Progress Summary		

• 1st Quarter Financial Report • Invoice for $		
• Continuation Request • New Budget Review		
• 2nd Quarter Progress Summary • 2nd Quarter Financial Report • Invoice for $		
• 3rd Quarter Progress Summary • 3rd Quarter Financial Report • Invoice for $		
• Final Narrative Progress Report • Research Milestone Chart • Final Financial Report	Life of the Grant	≤ 60 days after the end of grant period
• Final Invoice is based on a reconciliation of all cost associating with project not to exceed		≤ 60 days after the end of grant period
Only if requesting a No Cost Extension: • Annual Narrative Progress Report Research Milestone Chart		

Sample. Subject to revisions