



James and Esther King Biomedical Research Program

Announcement of Funding Opportunity and Call for Applications

Spring FY 2013-2014

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Call for Grant Applications: FY 2013-2014**

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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
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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.

The Florida Department of Health announces a funding opportunity for research and the development of enduring research infrastructure/resources addressing the prevention, diagnosis, treatment, and/or cure of diseases related to cancer, cardiovascular disease, stroke, and pulmonary disease (“tobacco-related diseases”). For this solicitation, 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 describe below. Organizations will only be permitted to be the lead on one application, but may be collaborators on applications submitted by other organizations.

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 the state, 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.

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 Call for Grant Applications are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Call for Grant Applications, 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 Call for Grant Applications, all applicants acknowledge this requirement. The "Terms and Conditions" also include the post-award schedule of deliverables.

2. Highlights

- Application instructions will be available on or about May 5, 2014 at the program website:

<http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html>
- Eligible organizations may submit an infrastructure application in one of the six areas listed. Organizations will only be permitted to be the lead on one application, but may be collaborators on applications submitted by other organizations.
- All applications must be submitted by the date indicated in I.3, 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.3, Table 1.
- There is a defined question and answer timeframe as indicated in I.3, Table 1. All questions will be answered at **one** time on or around the date indicated in I.3, Table 1.
- When research 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 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, Call amendments, and answers to programmatic questions.

3. Schedule of Important Dates

Table 1. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Funding opportunity announced	On or around April 14, 2014	Located at: http://www.floridahealth.gov/provider-and-partner-resources/research/funding-opportunity.html
Online application system opens	On or around May 5, 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 April 25, 2014	E-mail questions to: research@flhealth.gov
Answers posted to written questions	One time on or around May 2, 2014	Questions and answers will be published on the program website
Applications due	Applications must be submitted before 5:00 p.m. EST May 12, 2014	Applications must be submitted through https://biomed.fluidreview.com/
Awards announced	On or around June 16, 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 June 24, 2014

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 IRB review procedures for biomedical grant program research.
Grants begin	July 1, 2014	Contingent on verification of all eligibility requirements and regulatory approvals.
Proposal evaluation summaries available to applicants online	On or around August 15, 2014	The evaluation report will be available to applicants at: https://biomed.fluidreview.com/ The Principal Investigator 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.

A. Award Amount and Duration

1. The maximum award is \$1,600,000 in total costs (including direct and indirect costs).
2. Awards are for up to 36 months.

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).

For this solicitation, eligible organizations may submit an infrastructure application in one of the six areas listed. Organizations will only be permitted to be the lead on one application, but may be collaborators on applications submitted by other organizations.

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. For the purposes of this program, 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 grants and grant applications.

Council members shall not:

- Receive any form of financial compensation from a James & Esther King 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 Calls for Grant Applications, 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 shall not:

- 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.
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.

Table 2. Grant Application Components and Page Limits

Section	Category	Page Limit	Comment
E*	Type of Infrastructure	1500 characters	Required. Identifies the proposed infrastructure project of tissue banking, bioinformatics, genomics, diagnostic imaging, health disparities or quality indicator system and plan for sustaining infrastructure.
F*	Health Impact	1500 characters	<p>Applicants 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.</p> <p>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.</p>
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
<p>* (Sections A-G) Submitted materials are subject to the provisions of Art. I, Sec. 24, <i>Florida Constitution</i> and Chapter 119, <i>F.S.</i>, Florida's public records laws. These laws grant anyone the right to inspect any public record. <u>Applicants are discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application.</u></p> <p>** (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.</p>			

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 Call

This Call for Grant Applications is issued by the Florida Department of Health. The Public Health Research Unit manages the Call for Grant Applications, 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.3, 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/oqa/> 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.fluidreview.com/>) will be available to accept applications for this Call on or about May 5, 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.3, 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.3, 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.3. 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 Call for Grant Applications. 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.3 will be disqualified.

Each application submitted by the deadline indicated in Table 1 of I.3 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 Call for Grant Applications 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 Call for Grant Applications 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, 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 now 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.fluidreview.com/> on or around August 15, 2014.

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.3.

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

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.	
<div style="border: 1px dashed black; padding: 5px;"><input type="checkbox"/> Ownership interest, stock options, or other financial interest of any value related to the research. Does not include mutual funds or companies publicly traded on a stock exchange.</div>	
<input type="checkbox"/> Compensation of any value related to the research.	
<input type="checkbox"/> Proprietary interest related to the research of any value including, but not limited to, a patent, trademark, copyright or licensing agreement.	
<input type="checkbox"/> Board or executive relationship in a company (such as a startup company but including publicly traded companies) related to the research, regardless of compensation.	
<input type="checkbox"/> Any arrangement where the value of the ownership interests will be affected by the outcome of the research. For example, an arrangement has been made where the value of stock options given to the researcher by a startup company will vary depending on the outcome of the research.	
<input type="checkbox"/> Any other interest that could be affected by the outcome of the research	
If any of the following above conditions are met, provide a description of financial interests related to the research:	

<input type="checkbox"/> The grantee has no financial interests requiring disclosure	

Signed _____	Dated _____
Failure to disclose financial interests related to the research, and failure to provide an updated disclosure at least at the time of the continuation request or if the financial interests of the researcher and personnel on the grant change, may result in:	
- Immediate termination of the grant.	
- Financial consequences, including repayment of all grant funds.	
- Any other action required by state law.	

**Sample. Subject to revisions.

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.