James and Esther King Biomedical Research Program

Announcement of Funding Opportunity and Call for Applications

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James and Esther King Biomedical Research Program
Call for Grant Applications: FY 2013-2014

NOTE: Only applications received through the GrantEase™ online application system will be accepted.

Applicants must register online at www.floridabiomed.com/login.html to be able to submit an application. Previously registered applicants will have to re-register, although the same user name and password can be used. See Part III for application preparation and submission instructions.

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

Technical Support
Solix Inc.
Grant Management Solutions
(816) 347-9449 (phone)
techsupport@floridabiomed.com (E-mail)

If you experience technical difficulties during the final hours of the competition, please contact technical support immediately for assistance.

PART 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 Florida Legislature specified 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 prevention, diagnosis, treatments, and cures of diseases related to tobacco use, including 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 biomedical research by undertaking new initiatives in 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.

In pursuit of these goals, **the Program is soliciting applications** from eligible institutions to fund initiatives addressing the prevention, diagnosis, treatment, and/or cure of diseases related to tobacco use such as cancer, cardiovascular disease, stroke, and pulmonary disease.

In this Call, the Department gives priority to research proposals that address the following:

- Tobacco control, tobacco education, prevention of tobacco use, or nicotine addiction; and the health needs of current and/or former tobacco users

- Health systems and epidemiological research, particularly research involving the Florida Cancer Data System

- Translational research

- Community-based participatory research

- Cancers with significant public health impact, such as cancers of the lung, breast, and colon

- Health disparities

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 Part II, Chapter 7 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. An example Form DH FBRP 2012, Florida Biomedical Research Programs, James and Esther King Biomedical Research Program and Bankhead-Coley Cancer Research Program Terms and Conditions is located on the Program website and can be accessed by clicking on the following link: Terms and Conditions (www.floridabiomed.com/jek_call).

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

- Detailed application instructions will be available at http://www.floridabiomed.com/jek_call on or before July 15, 2013.

- Each grant mechanism has its own Call for Grant Applications.

- All applications must be submitted by the date indicated in Part I, Chapter 4, 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 Part I, Chapter 4, Table 1.

- There is a defined question and answer timeframe as indicated in Part I, Chapter 4, Table 1. All questions will be answered at **one** time on or around the date indicated in Part I, Chapter 4, Table 1.

- 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 Part II, Chapter 8, Definitions, for more information about the Federal Executive Pay Scale.

- Applicants are encouraged to check the Program website at www.floridabiomed.com 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
Competition opens for online applications	**On or about July 15, 2013**	Visit www.floridabiomed.com and register for access to an online application.
Written questions accepted	**QUESTIONS MAY BE SUBMITTED ANY TIME UNTIL 5:00 PM EST JULY 15, 2013**	E-mail questions to: questions@floridabiomed.com
Answers posted to written questions	**One time on or around July 22, 2013**	Find questions and answers at http://floridabiomed.com/king_qa.html
Online applications due	**APPLICATIONS MUST BE SUBMITTED BEFORE 5:00 PM EST July 31, 2013**	Online applications must be submitted through www.floridabiomed.com
Proposal evaluation summaries available to applicants online	On or around October 30, 2013	For all eligible and qualified applications, the evaluation report will be available to the applicant by logging in at www.floridabiomed.com. The Principal Investigator will be notified when the evaluation report is available.
Awards announced	On or around September 30, 2013	Award letters will be E-mailed to the Administrative Official and the Principal Investigator. All unfunded applicants will also be notified.

Regulatory approvals due (if applicable)	Immediately after award notification, grantees should submit all necessary applications to regulatory authorities including, but not limited to the IACUC and IRB. Project work may not begin until all approvals are provided. The IRB and IACUC 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 www.flpublichealthethics.net for Guidance on IRB review procedures for Biomedical grant program research. Guidance will be posted on the program website on or about July 22, 2013
Grants begin	October 1, 2013	Contingent on verification of all eligibility requirements and regulatory approvals.

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

PART II. ELIGIBILITY AND APPLICATION REQUIREMENTS

1. Tobacco-Relatedness

All applicants must clearly demonstrate how the proposed project is relevant to tobacco use or the diseases related to tobacco use. **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 $400,000 in total costs (including direct and indirect costs).

2. Awards are for up to 24 months.

2. Eligibility Requirements

A. Eligible Applicants

The applicant must be an eligible institution (see the definitions provided in Part II, Chapter 8), and all awards will be made to institutions, not individuals.

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 Part II, Chapter 8).

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 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, or a postdoctoral fellow in his/her final fellowship year, by the time the application is submitted. Postdoctoral applicants must be a Full-time Faculty member or equivalent by the grant start date. Temporary faculty members, even though full-time, are not eligible to apply. See Full-time Faculty and Full-time Equivalent definitions in Part II, Chapter 8.

An applicant is not required to be a U.S. citizen or permanent resident; **however, 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.**

Principal Investigators who move to another eligible institutional during the award period must submit a written request and obtain Department approval prior to moving the grant to the new institution.

General information regarding the project and specific information about the Principal Investigator and the applicant organization will be collected in the *General Project Information* section of the application. Detailed application instructions will be available at http://www.floridabiomed.com/jek_call on or before July 15, 2013.

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 http://www.floridabiomed.com/council.html.

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.

The Principal Investigator **may**:

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

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.

D. Application Resubmission

Previously unfunded King or Bankhead-Coley applications can be resubmitted only **one time**.

3. Required Grant Application Components

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

MAXIMUM UPLOADED SINGLE FILE SIZE: 3 MB

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 GrantEase™. **File sizes greater than 3 MB will not upload.** Detailed application instructions will be available at http://www.floridabiomed.com/jek_call on or before July 15, 2013.

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.
E*	Key Personnel	1	Required. Identifies all key personnel.

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

Table 2. Grant Application Components and Page Limits			
Section	**Category**	**Page Limit**	**Comment**
* (Sections A-E) 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 F-N) 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
- 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 Part II, Chapter 8, 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:

It is the intent of the Program that activities funded through the Program, including data analysis, occur in Florida. Ninety percent of work (effort) must occur and 90% of funds must be spent in Florida at the applicant organization and any collaborating entities. Funding for any out-of-state personnel or consulting expenses cannot exceed 10% of the total requested direct costs. This out-of-state limitation does not include lab services, supplies, or equipment.

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. Consortium indirect costs are also limited to 15%. The institution and the consortium/contractor cannot both charge indirect costs on the consortium/contractor direct costs, one or the other may charge indirect costs.

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
- 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 Program on behalf of the State of Florida, Department of Health. Solix, Inc., the Department's contracted agent for managing the Call for Grant Applications, accepting applications, and conducting peer review, is responsible for answering all applicant questions. Applicants and persons acting on their behalf may contact Solix in writing via E-mail as indicated below regarding programmatic issues. Applicants who attempt to 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 questions@floridabiomed.com.

Answers to questions will be available on the Program website, http://floridabiomed.com/king_qa.html. Answers to Frequently Asked Questions will be posted to the website when the Call for Grant Applications is released. Answers to submitted questions will be posted one time on the website, according to the schedule in Part I, Chapter 4, Table 1. Applicants are responsible for checking this website regularly throughout the application, peer review, and award processes for Program announcements.

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:

Technical Support
Solix, Inc.
(816) 347-9449 (phone)
techsupport@floridabiomed.com (E-mail)

If you experience technical difficulties during the final hours of the competition, please contact technical support immediately for assistance. The Department recommends that applications be submitted early and that you do not wait until the last day.

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).

Established Research Institute: An established research institute eligible for Program funding is an organization that is any Florida nonprofit or foreign 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. This includes federal government and non-profit medical and surgical hospitals including Veteran's Administration hospitals.

Feasibility: The practical extent to which a project is capable of being successfully performed within the requested time and for the awarded money. With regard to commercialization, feasibility refers to the potential that a project demonstrates for further development activities.

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 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.

PART III. INSTRUCTIONS FOR APPLICATION PREPARATION AND SUBMISSION

1. General Instructions for Application Submission

All applications must be prepared and submitted online through the online application system, GrantEase™, accessible from the Program's website, www.floridabiomed.com. Paper applications will not be accepted. **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 scanned and included in the appropriate section of the application as indicated in the online instructions. Online applications without 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 only have access to the online application and do not receive applications in paper format.

A. Technical Assistance

For technical assistance completing an application (i.e. how to upload a file) username and password problems, etc.), login at the Program website at www.floridabiomed.com and use the Live Help feature or contact Solix, Inc. via E-mail at programsupport@floridabiomed.com or by phone at (816) 347-9449.

If you have questions regarding interpretation of the Call language or other programmatic questions about the Call, see Part II, Chapter 6 A, for the appropriate process to submit those questions.

B. Online Registration and Application Submission

Only applications received through the GrantEase™ online application system will be accepted. The GrantEase™system will be available to accept applications for this Call on or about July 15, 2013.

To complete the online application process:

1. **Applicants must register to access the online application and forms.** Register for an online application at http://www.floridabiomed.com/login.html 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. Everyone, including previous applicants, must register to obtain access to the online application process.

2. Log in at http://www.floridabiomed.com/login.html. If you are a new applicant you will be prompted to change the assigned temporary password.

3. Complete the online application form for the appropriate grant mechanism. Detailed application instructions will be available at http://www.floridabiomed.com/jek_call on or before July 15, 2013. **Certain sections of the application include downloadable Microsoft Word™ or Excel™ forms to simplify preparation and submission. All forms can be found in the online application by clicking on the Application Form Templates menu link. Do not alter the forms.** 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.

4. **A login username is intended to be used by one person at a time. Unpredictable results can occur if multiple people are using the same login ID (username) and are updating the application at the same time.**

5. Some forms, such as the Cover/Certification Page and Budget Form require signatures. Do not wait until minutes before the deadline to obtain the required signatures. Applications may be disqualified if appropriate signatures are not on required forms or letters.

6. When the Word and Excel forms are completed, convert each file to Adobe Acrobat™ (PDF) format. The conversion to PDF will require access to the full Adobe Acrobat™ software product. This is a separately licensed software product from Adobe, not to be confused with the free Adobe Acrobat Reader™ that is used only to view PDF-formatted documents. Specifications and ordering information for either the full Adobe Acrobat™ software package or an online conversion subscription service can be found at Adobe's website, www.adobe.com/products/acrobat/main.html. It is the sole responsibility of the applicant to make sure that this conversion to PDF format is completed successfully. The maximum uploaded file size is shown in Part II, Chapter 4. See Appendix A for tips on how to reduce PDF file sizes.

7. Save all completed forms and files with descriptive file names of 30 characters or less and be sure to only use standard characters in file names: A through Z, a through z, 0 through 9, and underscore (_). Do not use any special characters (example: “&”, “-“, “*”, “%”, and “#”) or spacing in the file name.

8. Return to the website to work on the application at any time prior to submission. All required fields and sections must be completed before an application may be submitted. **Once submitted, applications cannot be modified. If an application is accidentally submitted, contact technical support (see Part III, Chapter 1 A) for assistance.**

9. 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 technical assistance (identified in Part III, Chapter 1 A), and the application can be unsubmitted so that the applicant can change and resubmit the application. The change and resubmission must occur before the application deadline as shown in Part I, Chapter 4, Table 1.

C. General Application Guidelines

1. An application should be written with the care and thoroughness given to manuscripts for publication. Review the application carefully to ensure that information necessary for evaluation is included. The scientific and technical merit of the proposed project is the primary concern for peer review.

2. Read and follow all instructions carefully to avoid delays and misunderstandings. Address each section of the application clearly and precisely.

3. Applications must be legible and in English.

4. 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.

5. **Observe the character and page number limitations**. A summary of these limitations is given in Part I, Chapter 4, 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.

6. **File sizes greater than 3 MB will not upload**.

7. Before it can be submitted, the application must contain all of the required sections identified in Part I, Chapter 4, 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.**

PART 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 Part I, Chapter 4. The Program 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.

If you submit your application and want to change the application before the submission deadline, contact Technical Support (identified in Part II, Chapter 6 B) for assistance.

2. Evaluation of Applications

The Program will use a multi-step evaluation process before making award determinations for all applications submitted in response to this Call for Grant Applications. The Program 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 Part I, Chapter 4 will be disqualified.

Each application submitted by the deadline indicated in Table 1 of Part I, Chapter 4 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 Program 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

Program peer reviewers will assess the overall impact of all qualified/eligible applications, and at the discretion of the Program 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 and will receive instructions on the avoidance of conflict-of-interest. 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

Qualified/eligible applications will be assigned to three independent peer reviewers. Each reviewer will submit their independent ratings and comments online to Solix. During the evaluation process, reviewers will not be able to see critiques by the other reviewers assigned to the same or other application(s). For each application, the three overall impact scores will be averaged to determine the overall score. All peer reviews will be complete by the date and time indicated in Part I, Chapter 4, Table 1, after which time the reviewers will be able to see only the final evaluation reports for the applications they evaluated.

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.

Peer reviewers only have access to the online application and do not receive applications in paper format.

Specific questions that will be used by the peer reviewers are available on the Program website at www.floridabiomed.com/jek_call.

C. Programmatic Review

The Department and the Florida Biomedical Research Advisory Council will consider the Program peer review scores/rankings and Program 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. Applications with a high overall impact may be excluded from the list of recommended projects for programmatic reasons including the relevance of the research to diseases related to tobacco use. (See Part II, Chapter 1 for tobacco-relatedness description.)

D. Evaluation Reports

For all eligible and qualified applications, the evaluation report will be available online to the applicant on or around October 30, 2013. To access the evaluation report, the applicant must log in at www.floridabiomed.com using the same log in username and password used for the application process.

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 Part I, Chapter 4. Applications deemed fundable but not awarded due to budget limitations will remain active for one year from the date of submission. The Program may fund these applications if monies become available. Prior to making an award decision, the Department may ask applicants to update and verify their application. This additional information shall in no way alter or extend the one-year criterion.

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. An example of the "Terms and Conditions" is located on the Program website and can be accessed by clicking on the following link: Terms and Conditions (www.floridabiomed.com/jek_call). **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. The "Terms and Conditions" include the post-award schedule of deliverables.

Additionally, this Program is a state program, and therefore all grantees are recipients/sub-recipients of state financial assistance.

B. Grantee Reporting Requirements

If the applicant's proposal is funded, the Grantee must respond to Program 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.

Refer to the Program website at www.floridabiomed.com/jek_call to review the "Terms and Conditions," which includes the full post-award deliverable schedule.

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 this Program are encouraged to use materials 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 Program funded projects/research. For more information on the NIH Open Access Policy visit http://publicaccess.nih.gov/.