



**JAMES & ESTHER KING
BIOMEDICAL RESEARCH PROGRAM**

**Special Call for Grant Applications:
Shared Instrument Grant (SIG)
for Tobacco-Related Diseases
Fiscal Year 2009-2010**

**Florida Department of Health
Office of Public Health Research
Tallahassee, Florida**



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Special Call for Grant Applications: Shared Instrument Grant, FY 2009-2010**

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1. INTRODUCTION

The James and Esther King Biomedical Research Program (hereafter referred to as the "Program"), established in section 215.5602, *Florida Statutes* (s. 215.5602, *F.S.*), supports research for the prevention, diagnosis, treatment, and cure of tobacco-related diseases. The Program receives funding from two sources. Part of Program funding comes from interest earned on a portion of the Lawton Chiles Endowment Fund, a fund established with monies received from the tobacco industry through Florida's tobacco lawsuit settlement agreement. Beginning in the 2009-2010 fiscal year (FY), the Program will also receive 2.5%, not to exceed \$25 million, of the revenue deposited into the Health Care Trust Fund from the increased cigarette user fee imposed by s. 210.02, *F.S.*

Due to the increase of available funds in FY 2009-2010, the Program is issuing Special Calls for Grant Applications for grants expected to begin on or about January 1, 2010.

The Florida Department of Health, through the Office of Public Health Research (hereafter referred to as "the Department") administers the Program with the support of a contracting partner, the Lytmos Group, Inc. The Program also solicits recommendations and suggestions on policy alternatives from the Biomedical Research Advisory Council consistent with s. 20.435, and s. 215.5602, *F.S.*

The Program has five long-term goals:

1. Improve the health of Floridians by researching better prevention, diagnoses, 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, diagnoses, 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 **Shared Instrument Grant (hereafter referred to as "SIG")** applications from eligible institutions to fund initiatives addressing the prevention, diagnosis, treatment, and/or cure of tobacco-related diseases such as cancer, cardiovascular disease, stroke, and pulmonary disease.

Through separate Calls, the Department is also soliciting grant applications for two other grant mechanisms:

- 1 Florida Research Challenge (Florida RC1) Grant
2. Technology Transfer/Commercialization Partnership (TTCP) Grant

This Call for Grant Applications applies only to SIG applications. To access the Florida RC1 and TTCP Calls for Grant Applications, visit the Program website www.floridabiomed.com.

The Program has historically operated in general accord with the policies and procedures for extramural funding employed by National Institutes of Health (NIH) and looks to the NIH as a source of standard practices. To protect the credibility of the Program and to ensure public trust, this general accord includes but is not limited to similar expectations of adequate institutional control and oversight to guard against financial conflict of interest, scientific misconduct, scientific and financial overlap and the mismanagement of funds, the protection of human and vertebrate animals, and compliance with applicable state and federal laws or regulations.

All awards in response to this Call are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Call, 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 of the "Terms and Conditions" is located on the Program website and can be accessed by clicking on the following link: [Terms and Conditions \(www.floridabiomed.com/jek_call\)](http://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, all applicants acknowledge this requirement. The Terms and Conditions also include the post award deliverables schedule.

2. HIGHLIGHTS

- Each grant mechanism has its own call for applications and instructions documents.
- The instrument must be operational by the end of the one year grant period. See Chapter 4.
- A Management Plan Overview is required for the application. The complete Management Plan will be a deliverable due with the first quarter invoice if a grant is awarded. See Chapter 5.
- The award may include an additional expense of up to \$50,000 for required physical modifications to the site in order to accommodate the instrument. See Chapter 6.
- A link to the peer reviewer questions has been added to Chapter 11.

- Tips for reducing file sizes have been added to Chapter 14F.
- The Question and Answer process has been improved. Answers will be posted to the website frequently as questions are received. See Chapters 9 and 10.
- Definitions of key terms used throughout this document are located in Chapter 15.

3. TOBACCO-RELATEDNESS

All applicants must clearly demonstrate how the proposed project is relevant to tobacco use or tobacco-related diseases. Grant requests must support the work of **biomedical and biotechnological research** addressing the etiology, pathogenesis, prevention, diagnosis, treatment, and/or cure of tobacco-related diseases 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, or nicotine addiction; and/or address the health needs of current and/or former tobacco users. Applicants who do not or cannot demonstrate the relatedness between tobacco and the proposed project will not be funded.

4. SHARED INSTRUMENT GRANT (SIG) MECHANISM INFORMATION

The intent of the Shared Instrument Grant (SIG) mechanism is to support Florida investigators who are conducting tobacco-related research by improving access to state-of-the-art research instruments that can only be justified on a shared-use basis and for which meritorious tobacco-related research projects are described.

Proposals may be for a single instrument, a large system of instruments, or multiple instruments that share a common or specific research focus. Instruments must cost at least \$100,000 and no more than \$500,000. If the amount of funds requested does not cover the total cost of the instrument, the applicant must describe the proposed source(s) and amount of funding for the balance of the cost of the instrument in the institutional letter of commitment.

Instruments purchased with this grant must remain in the state of Florida. All instruments purchased with grant funds will be the property of the eligible institution, not the principal investigator, and are subject to Chapter 273, *F.S.*, dealing with state-owned tangible personal property and the disposition thereof. For research institutions not covered under Title XLVIII of the *Florida Statutes*, instruments no longer deemed useful shall be transferred or donated to a state agency or public university for redistribution or disposition.

A. SIG Award Amounts and Duration

1. The award is between \$100,000 and \$500,000 maximum.
2. Awards are for a period of 12 months.

3. Grants will begin on or around January 1, 2010 and end December 31, 2010.
4. Purchases must be made, the institution must have accepted invoices for payment, and the instrument must be operational before December 31, 2010.
5. SIGs are not eligible for future non-competitive continuation support.

5. ELIGIBILITY REQUIREMENTS

A. 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 research. For more information on the NIH Open Access Policy visit <http://publicaccess.nih.gov/>.

B. Eligible Applicants

The applicant must be an eligible institution. (See the definitions provided in Chapter 15.) 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 shall include:

- State universities - A state university is defined in s. 1001.60, *F.S.*, except as otherwise specifically provided, as the 11 named public, postsecondary institutions and any branch campuses, centers, or other affiliates of the institution. For purposes of the Program, the named university or college and any branch campus, centers or affiliates, unless it can be legally shown otherwise, are considered one and the same, and where the number of applications is limited, the university and its branch campuses, centers or other affiliates must coordinate submission(s) in order to comply with the limitation. Questions regarding an institution's independence must be submitted in writing during the question and answer period (see Chapter 9 for dates). Public institutions must be accredited by a nationally recognized organization.
- Nonpublic institutions - For the purposes of the Program, nonpublic institutions operating under Chapter 1005, *F.S.* are also eligible. Any branch campuses, centers or other affiliates of a nonpublic institution are considered one in the same with that institution,

and 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. Questions regarding an institution's independence must be submitted in writing during the question and answer period (see Chapter 9 for dates). Nonpublic institutions must be accredited by a nationally recognized organization.

- Established research institutes - An established research institute is defined as any Florida nonprofit or foreign nonprofit covered under Chapter 617, *F.S.*, with a physical location in Florida, whose stated purpose and power is 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.

Applications may be submitted by any eligible institution. SIG applications will be limited to three per eligible institution and each application must request support for different instruments. Applications for the same project cannot be submitted to the Bankhead-Coley Cancer Research Program. More than three SIG submissions from the same institution will result in the rejection of all SIG applications from that institution until clarification is received from that institution regarding which three applications shall be the submissions. The Program will correspond with the parties involved via certified mail, and the institution will be given five business days to respond. Failure to respond in a timely fashion will result in the rejection of all SIG applications from the institution.

Principal investigators from eligible institutions may apply for funding from the Program. The eligible institution, 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.

To be eligible as a **Principal Investigator at an eligible institution**, the individual must be a full-time faculty member at an eligible institution, or a postdoctoral researcher in his/her final fellowship year, by the application due date of September 18, 2009. Postdoctoral applicants must be a Full-time Faculty member or equivalent by December 4, 2009. Temporary faculty members, even though full-time, are not eligible to apply. See Full-time Faculty and Full-time Equivalent definitions in Chapter 15.

C. Additional Application Requirements and Limits

The requested instrument must be commercially-available equipment, or an integrated instrument system that is technologically sophisticated.

The proposal must include an assurance that the requested instrument will be used by a minimum of three independent investigators from three separate user groups (department, office, laboratory, or equivalent) for at least three different projects. Each of these three major projects should demonstrate a need for the instrument for tobacco-related research. It is incumbent upon the applicant to show how obtaining the instrument will further the search for prevention, diagnosis, treatment, and/or cure of tobacco-related diseases.

In no case may more than 60% of the instrument's time be allocated to one research group and its collaborator(s).

The application must show a clear need for the instrument by projects supported by current or proposed tobacco-related research grants and demonstrate that these projects will require at least 75% of the total possible usage of the instrument.

An **institutional letter of commitment** is required. This letter must specifically describe the institutional infrastructure available to support the instrument. Provide documentation (e.g., separate letters signed by appropriate institutional officials) specifically describing the institutional commitment (in dollars) in support of the proposed plan.

An **advisory committee** must be named to assist the Principal Investigator in administering the grant and overseeing the responsibility for the instrument. The membership of this committee should be broadly based and include members without conflicts of interest who can resolve disputes if they arise. The Principal Investigator and the advisory committee are responsible for the development of guidelines for:

- The development of guidelines for maximum use of the instrument, including time allocation.
- A detailed plan for the day-to-day management and safe operation of the instrument.
- If appropriate, a plan to ensure that access to the instrument is limited to users whose projects have received approval by institutional human subjects, animal welfare, or biosafety committees.
- A financial plan for the long-term operation and maintenance of the instrument after the grant period.
- A training plan for relevant staff to use the instrument.
- The relocation of the instrument within the institution if the major user group is significantly altered.

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

Applicants may not submit duplicate projects or projects with significant scientific or financial overlap to different mechanisms within the James & Esther King Biomedical Research Program for the same Call for Applications. Applicants may also not 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 for the same Call for Applications. The Principal Investigator may submit two or more completely different projects at the same time.

If the applicant's proposal is funded, grantees must submit an instrument management plan, thirty days after the end of the first quarter, describing the development guidelines (above) created by the advisory committee.

If the applicant's proposal is funded, the Grantee must submit a Final Progress Report, thirty days after the end of the grant period, describing the instrument purchased and providing a list of all users and a description of the value of the instrument to the investigators and to the institution as a whole.

If the applicant's proposal is funded, the Grantee must make annual project impact reports to the Program for a period of five (5) years after the end of the grant period, or for the length of the useful life of the instrument, whichever is shorter. These reports must include effectiveness of management plan, advisory committee status, user log status, usage information, and instrument benefits. In addition, the Grantee must respond to Program requests for information during the same period, to report on the long-term outcomes based on research performed using the instrument, including the value of additional grant awards for tobacco-related research that utilize the instrument, a list of tobacco-related presentations, a list of tobacco-related publications in peer-reviewed journals, and any invention disclosures, patent filings, patents received, et cetera.

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

6. ALLOWED AND DISALLOWED COSTS

The following information explains direct and indirect costs allowed by the Program, as well as disallowed costs. Additional budget instructions are available online with the application form, which is accessible after the applicant registers and logs in to the online system at www.floridabiomed.com. See Chapter 7 for registration instructions.

A. Allowed Project Costs

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

- instrument upgrade or initial purchase
- installation
- commissioning
- calibration
- Computer systems, clusters of advanced workstations, networks, and other information infrastructure components necessary for research

The amount requested in the proposal should be based on the net price of the equipment, including all academic discounts and other special purchase arrangements.

The budget may include up to \$50,000 in addition to the cost of the equipment for physical alterations (see definition for "physical alteration" in Chapter 15) necessary to accommodate the instrument. The total grant amount will not exceed \$500,000.

It is the intent of the Program that activities funded through the Program, including data analysis, occur in Florida. Eighty percent of effort and funds must occur in Florida at the eligible institution and any partnering entities. Funding for any out-of-state personnel or consulting expenses cannot exceed 20% of the total requested direct costs. This does not include lab services, supplies, or equipment.

B. Disallowed Project Costs

All costs must be specifically and directly related to the project, necessary for the project's completion, and adequately justified. Any other costs are disallowed. Additionally, the following items shall NOT be purchased with grant funds, and proposals seeking funding for these items may not be peer-reviewed:

- computer networks as general equipment
- lists of assorted instruments or general lab equipment that do not share a common or specific research or research training focus
- renovation or modernization of research facilities; the term "research facilities" refers to the bricks-and-mortar physical structure in which research activities (including research training) take place, including related infrastructure systems (e.g., HVAC and power systems, toxic waste removal systems)
- fixed equipment; the term "fixed equipment" refers to the permanent components of a research facility that are integral (i.e., built in, rather than affixed) to the facility (e.g. clean rooms, fume hoods, elevators, laboratory casework), and whose removal would affect the integrity or basic operation of the facility
- instrumentation for purely instructional purposes
- costs of instrument maintenance and operations
- instrument development projects
- direct and indirect costs associated with research projects to be conducted using the requested instrument (including researcher's salary, students' stipends, project supplies and travel)

7. ONLINE APPLICATION REGISTRATION

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. Data collected during registration includes basic contact information, proposal subject, brief proposal description, and the grant mechanism of interest. Registered applicants will receive a username and password that will allow access to the online application system.

See Chapter 14 for application submission instructions and Addendum 1 for specific field-level instructions. Application instructions are also included with the online application, which is accessible after registering and logging into the online system at www.floridabiomed.com/login.html.

8. REQUIRED SIG APPLICATION COMPONENTS

A complete Shared Instrument Grant application package **must** contain all required items listed in Table 1.

TOTAL MAXIMUM PAGE LIMIT: 45 printed pages

TOTAL MAXIMUM UPLOADED FILE SIZE: 1 MB

Includes cover/certification page and all required and optional sections. Proposals exceeding the page limits where specified are subject to truncation to the page limit or may be disqualified without review. Proposals exceeding the total maximum page limits will be returned without review. For information on how to reduce file sizes, see Chapter 14 F, or contact technical support via email at techsupport@floridabiomed.com.

Table 1. SIG Application Components and Page Limitations			
Section	Category	Page Limit	Comment
General Project Information:			
A	General Research Information*	2	Required. This section includes general project information.
B	General Audience Abstract*	1500 characters	Required. This section must explain the proposed project in layman's terms, including its relationship to the goals of the Program.

Table 1. SIG Application Components and Page Limitations			
Section	Category	Page Limit	Comment
C	Tobacco-Relatedness*	3000 characters	Required. This section must provide a clear explanation of how the project is related to tobacco use or tobacco-related diseases.
D	Proposed Tobacco-Related Research Activities**	8	Required. This section must contain a description of the tobacco-related research and research training to be conducted with the proposed instrument, including a list of personnel who will use the instrument on a regular basis.
E	Description of Instrument and Need*	3	Required. This section must contain a technical description of the requested instrument, an estimate of its useful life, and justification of the necessity and adequacy of the new instrument for the proposed research projects, with reference to existing instruments.
F	Management Plan*	4	Required. This section must specify how and by whom the requested instrument will be operated over its useful life.
G	Advisory Committee	1	Required. This section must identify the advisory committee that will assist the PI in the administrative/scientific oversight of the instrument.
H	Budget	4	Required. The budget must explain the planned spending for the proposed work.
I	Institutional Letter of Commitment	2	Required. The letter must show the institution's commitment to support and maintain the shared instrument.
J	Biographical Sketches	4 per person	Required. Information must be provided for the Principal Investigator and the Chair of the Advisory Committee.
K	Vendor Itemized Quote	10	Required. At least one itemized quote for the proposed instrument from qualified vendor(s) must be included.

Table 1. SIG Application Components and Page Limitations			
Section	Category	Page Limit	Comment
L	Cover Page/Certification – Signed	1	Required. Original signed cover page must be delivered separately by due date as specified in Chapter 9. A PDF copy of the signed cover/certification page that was mailed to DOH must be uploaded.
TOTAL MAXIMUM PAGE LIMIT: 45 printed pages			
TOTAL MAXIMUM UPLOADED FILE SIZE: 1 MB			
<p>* (Sections A-C, E, F) 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 a right to inspect any public record. There are some documents and information which are exempt from the public records laws. <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. If this is the case, DO NOT place such information in the General Research Information sections of the application. These sections are subject to publication and wide dissemination in the event you are awarded a grant.</u></p> <p>** (Section D) 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 which makes the document or information exempt from the public records laws. If a public record 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>			

9. SCHEDULE OF IMPORTANT DATES

The following schedule applies to all applications submitted in response to this Call for Grant Applications.

Table 2. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Competition opens for online applications	August 10, 2009	Visit www.floridabiomed.com and register for access to an online application.
Written questions accepted	QUESTIONS MAY BE SUBMITTED AT ANY TIME AFTER THE CALL IS PUBLISHED AND MUST BE RECEIVED BEFORE 5:00 PM EST SEPTEMBER 11, 2009	E-mail questions to: questions@floridabiomed.com
Answers posted to written questions	Updates will be made frequently to the website while the Call is open. Final updates will be posted on or around SEPTEMBER 15, 2009	Find questions and answers at http://floridabiomed.com/king_qa.html
Online applications due	APPLICATIONS MUST BE SUBMITTED BEFORE 5:00 PM EST SEPTEMBER 18, 2009	Online applications must be submitted through www.floridabiomed.com
Original signed cover/certification page due	COVER/CERTIFICATION PAGE(S) MUST BE POSTMARKED BY SEPTEMBER 18, 2009 FOR RECEIPT NO LATER THAN SEPTEMBER 22, 2009	Send signed cover/certification page(s) to the Biomedical Research Programs, Florida Department of Health address listed in Chapter 14 C.
Application peer review summaries available to applicants online	On or around December 1, 2009	Whether or not funding is awarded, the evaluation report will be available to the Principal Investigator by logging in at www.floridabiomed.com . The Principal Investigator will be notified by e-mail, when the report is available.

Table 2. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Awards announced	On or around December 4, 2009	Award letters will be mailed to the Sponsored Research Official. The Principal Investigator will receive notification by e-mail.
Grants begin	January 1, 2010	Contingent on verification of all eligibility requirements and regulatory approvals.

Dates after the application due date are subject to change. Changes will be posted to the Program website at www.floridabiomed.com. Applicants should monitor the website for changes and announcements.

10. 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. To ensure that no applicant receives an advantage over any other applicant, employees of the Department of Health and members of the Biomedical Research Advisory Council will not respond to questions regarding this Call for Applications until after all awards are announced. The Lytmos Group, Inc., the Department's contracted agent for managing the Calls for Applications, acceptance of applications, and peer review, is responsible for answering all applicant questions. Applicants and persons acting on their behalf may contact the Lytmos Group in writing via e-mail as indicated below regarding programmatic issues. Applicants who attempt to contact Department of Health and/or Biomedical Research Advisory Council members regarding this Call for 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 by the date and time shown in Chapter 9.

Answers to questions received before the deadline will be available on the Program website, www.floridabiomed.com by the date and time and at the specific location indicated in Chapter 9. Answers will be posted to the website frequently as questions are received. 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

Lytmos Group

(816) 347-9449 (phone)

techsupport@floridabiomed.com (e-mail)

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

11. 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

Each application submitted by the deadline indicated in Chapter 9 will receive an administrative review verifying mandatory eligibility requirements and the completeness of the application. The administrative review does not include review of the scientific merit.

Application materials not received according to the dates, times, and locations specified in Chapter 9 will be disqualified.

Any application failing to meet all administrative requirements may be ruled ineligible for funding in response to this Call for Applications and not entitled to further consideration. However, the Program may send ineligible proposals for scientific merit review in order to provide feedback to the applicant, which may be useful in competing for future funding opportunities.

B. Scientific Merit Review

Program peer reviewers will assess the scientific merit of all qualified/eligible applications. Peer review panels will be comprised of reviewers with expertise in the substance and methodology of the proposed project. 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 training 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.

In accordance with federal agency and state program best practices, peer reviewers will use a standard rating format: outstanding (1), excellent (2), satisfactory (3), fair (4), and unacceptable (5). Applications will be assigned to three independent peer reviewers. Each reviewer will submit their ratings and comments online to the Lytmos Group. During the evaluation process, reviewers will not be able to see critiques by other reviewers assigned to the same application, and will not be able to see applications or critiques assigned to other reviewers. All peer reviews will be complete by the date and time shown in Chapter 9, 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 SIG proposals for scientific merit using the following criteria:

- Relationship of the project to the advancement toward prevention, diagnosis, treatment and cure of tobacco-related diseases
- Justification of need for the proposed instrument
- Scientific and technical significance of the proposed research projects that will utilize the instrument
- Sufficiency of infrastructure and technical expertise to allow effective usage of the instrument
- Qualifications of the Principal Investigator
- Quality of the institutional commitment
- Proposed management plan

Reviewers will identify concerns regarding:

- The proposed budget

This information will be submitted along with the evaluations of scientific merit for consideration during the remainder of the funding process.

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 Florida Biomedical Research Advisory Council will consider the results of the Scientific Merit Review and peer review opinions and scores regarding tobacco-relatedness in a manner that is blind to investigator and institutional identities. In addition, Council members may take into account other programmatic interests, such as the balance of support among grant mechanisms and the availability of funds, in forming a set of funding recommendations to the State Surgeon General.

Applications with high scientific merit may be excluded from the list of recommended projects for programmatic reasons including the relevance of the research to tobacco-related diseases. (See Chapter 3 for Tobacco-relatedness description.)

12. NOTIFICATION OF FUNDING DECISION

Institutions and Principal Investigators will receive written notification of funding decisions. Applications deemed fundable but not awarded due to funding limitations will remain active for one year from the date of submission. The Program may fund these applications if funding becomes 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.

13. REQUESTS FOR RECONSIDERATION

All funding decisions of the State Surgeon General are final. After receiving the peer review scores and comments, the applicant may request a reconsideration by submitting a written statement outlining the substantive concern(s) and basis for the request. This written statement must be submitted by e-mail to programsupport@floridabiomed.com no later than five business days after notification of availability of the evaluation report.

A subcommittee of the Florida Biomedical Research Advisory Council (with the exception of recused members from the applicant's institution) will consider the merits of the complaint, and when warranted by apparent deficiencies in the peer evaluation, may order a reconsideration. The Program will provide a written response to the Principal Investigator containing the outcome of this process.

Based on the peer review scores, availability of funds, the pay line determined by the Biomedical Research Advisory Council in their funding recommendation to the State Surgeon General, and other factors, the application will be classified either as funded, fundable but unfunded, or unfundable. The best outcome an applicant can expect from a reconsideration is for his/her proposal to be more highly ranked as a result of a better score, placing that application in a better position if additional funding becomes available. However, the result also could be movement down the list of proposals. Reconsideration results are final.

14. INSTRUCTIONS FOR APPLICATION SUBMISSION

All applications must be prepared and submitted online through the online application system accessible from the Program's website, www.floridabiomed.com. Paper applications will not be accepted. Only the original signed cover/certification page of an application will be accepted as specified below. **Application materials not submitted in the specified manner, in the specified format, and by the specified deadlines outlined in Chapter 9 will be disqualified from competition.**

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 that **does not** give any applicant an advantage or benefit not enjoyed by other applicants, including extra time, 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.

A. Technical Assistance

For technical assistance completing an application, visit the Program website at www.floridabiomed.com and use the Live Help feature or contact the Lytmos Group via e-mail at programsupport@floridabiomed.com or by phone at (816) 347-9449.

B. Confidentiality of Submitted Materials

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. 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. However, if proprietary information is included, DO NOT put such information in the General Research Information sections of the application. These sections are subject to publication and wide dissemination if the applicant is awarded a grant. 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.

C. Original Signature Page and Other Materials

The original signed cover/certification page must be delivered to the Program according to the dates in Chapter 9. **All signatures must be in an ink color other than black (preferably blue) so the original is easily recognized.** Applicants are responsible for obtaining proof of delivery from the chosen delivery carrier.

The original signed cover/certification page must be delivered to the following address:

Biomedical Research Programs
Florida Department of Health
Office of Public Health Research

For United States Postal Service Mail Delivery:
4052 Bald Cypress Way
Bin A24
Tallahassee, FL 32399-1749

For Courier/Express Delivery (e.g., FedEx):
4030 Esplanade Way
Suite 280
Tallahassee, FL 32399

Contact number FOR EXPRESS DELIVERIES ONLY: (850) 245-4585

Required signature pages, such as the budget, and letter of commitment, must be scanned and included in the appropriate section of the application as indicated in the online instructions. **Scanned documents and originals must be identical.** Online applications without these pages will be disqualified.

Other documentation and materials, such as biosketches 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.

D. Online Application Submission

To complete the online application process:

1. Register as an applicant on www.floridabiomed.com/login.html and complete the brief project profile. Registration will be acknowledged with an e-mail message containing application instructions and a username and temporary password.
2. Log in at www.floridabiomed.com/login.html and change the assigned temporary password.
3. Complete the online application form for the appropriate grant mechanism. Field level instructions are available online with the application and in Addendum 1 of this document. Certain sections of the application include downloadable Microsoft Word or Excel templates to simplify preparation and submission. Do not alter the templates. 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, Management Plan, use only conventional alphanumeric letters and numbers (i.e., ASCII text) with no drawings, special characters or symbols.
4. 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 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 Table 1. See Chapter 14 F for tips on how to reduce PDF file sizes.)

5. Return to the website to work on the application at any time prior to submission and/or the deadline. All required fields and sections must be completed before an application may be submitted. **Once submitted, applications cannot be returned. If an application is accidentally submitted, contact technical support (see Chapter 14 A) for assistance.**

Important: It is the responsibility of the applicant to ensure that a complete application is submitted before the date and time specified in Chapter 9. Applicants should anticipate that the volume of online activity will increase as the application deadline approaches and this will slow upload times. The date and time stamp of receipt is based on when the upload is complete, not when the process began. Waiting until the deadline to complete significant portions of the application is not recommended.

E. General Guidelines

1. An application should be self-contained and written with the care and thoroughness given to manuscripts for publication. Review the application carefully to ensure that information necessary for evaluation is included.
2. Read and follow all instructions carefully to avoid delays and misunderstandings. Address each section of the application clearly and precisely.
3. Downloadable Microsoft Word or Excel file templates included as part of the application must not be altered in any way. Deviations may be grounds for the Program to reject the entire application.
4. Applications must be legible and in English.
5. 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, middle initial) in the designated space (upper right-hand corner) on each page of every uploaded document. All four margins 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, graphs, diagrams, tables, and charts. The application must contain only materials that, when scanned or converted to PDF format, are clear, sharp, and easy to read.
6. **Observe the character and page number limitations or the application may be returned without review.** A summary of these limitations is given in Table 1. Applicants are encouraged to confirm compliance with this requirement by printing the full application before submission. See Chapter 14 F for tips on how to reduce files sizes.
7. Before it can be submitted, the application must contain all of the required sections identified in Table 1. Uploaded files should be titled by the categories listed in Table 1

and page numbered within the template. **Appended material may not be used to circumvent the page limits for individual sections of the application.**

F. Reducing File Sizes

Below are some tips on reducing file sizes to meet Program application file size limitations.

- a. Compress images in the original Microsoft Word file before converting to PDF.

Embedded high-resolution images often lead to very large file sizes when a document is converted to PDF. To reduce file sizes prior to conversion, while in Microsoft Word:

- Right click on the image and select “Format Picture.”
- Select the “Compress” button.
- Select “Apply to > All pictures in document” and “Change resolution > Web/Screen.” Click “OK”

Check key images to make sure they are still clear enough for reviewers to interpret as they read your proposal. If not, Choose “Undo Compress Pictures” or selectively reinsert images at the lowest possible clear resolution, and use one or more of the next options for managing the overall size of your file.

- b. Compress a PDF file with Reduce File Size

Reduce the PDF file size with the “Reduce Files Size” feature in Adobe Acrobat. After completing this step make sure the file is still readable and includes everything intended.

- In Adobe Acrobat, go to “File > Reduce Files Size”

- c. Reduce PDF file size with ‘Save As’ rather than ‘Save’

Saving PDF files adds incremental updates to the original document, meaning any changes that you make to a document are appended to the end of the file without doing a complete rewrite. This is why the Save feature is much faster than a Save As, and also why PDF files saved this way can become very large. The Save As feature will rewrite the entire file and provide you with a smaller file size.

- In Adobe Acrobat, go to “File > Save As”

- d. Re-create the PDF to reduce PDF file size

A method of reducing PDF file size is to re-create the PDF by removing many unwanted objects, removing tags, and further compressing images. Any tool that supports ‘print to PDF’ functionality will allow this. Once again, check the clarity of key images to make sure they still add value to the proposal.

- e. Remove unwanted objects

For the greatest control of objects that are removed in the conversion process, such as bookmarks, links, annotations, form fields, JavaScript, Named Destinations, and embedded fonts, use optimizing features within the PDF software.

- In Adobe Acrobat, go to “Advanced > PDF Optimizer,” choose the objects to remove, and click “OK. “

15. DEFINITIONS

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.

Consortium or Contractual Agreement: An agreement whereby a research project is carried out by the Grantee and one or more other institutions 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 institution’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 institution. Consultants may also include firms that provide paid professional advice or services.

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.

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 veterans 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.

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 75% of the contracted services for the fiscal year. This includes tenured, tenure-track, and non-tenure track appointments.

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

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

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

Overlap, Scientific: Scientific overlap occurs when: (1) substantially the same research is proposed in more than one application or is submitted to two or more different funding sources for review and funding consideration, or (2) a specific research objective and the research design for accomplishing that objective are the same or closely related in two or more applications or awards, regardless of the funding source.

Physical Alteration: Changes the interior arrangements or other physical characteristics of an existing facility or of installed equipment so that it can be used more effectively for its currently designated purpose or adapted to an alternative use to meet a programmatic requirement. Examples of physical alternations include the temporary removal and replacement of wall sections and door frames to place equipment in its permanent location, or the costs of connecting utility lines, and installing any accessory devices required for the equipment's proper and safe utilization. Also, refer to Chapter 16 B for Disallowed Costs.

Principal Investigator: The one individual designated by the applicant institution to direct the project to be supported by the grant. The Principal Investigator is responsible and accountable to applicant institution 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. 1001.60, *F.S.*, except as otherwise specifically provided; as the 11 named public, postsecondary institutions and any branch

campuses, centers, or other affiliates of the institution. For purposes of the Program, the named university or college and any branch campus, center, or affiliate, unless it can be legally shown otherwise, are considered one and the same. 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.

16. FREQUENTLY ASKED QUESTIONS

1. What is needed before the application deadline? Is there a short letter of intent that is due earlier?

No document or correspondence is required before the Application and signed cover/certification page deadline. A letter of intent is not required. To obtain the application, you must complete the online registration as described in Chapter 7.

2. Is U.S. citizenship or a green card required before being awarded a grant?

No, United States citizenship or a green card is not a requirement.

3. Can faculty members at the same university but within different departments submit proposals?

Yes, all eligible investigators may submit an application regardless of the department; however, two investigators may not submit the same proposal where each is the co-investigator on the other's project.

4. Clarify the term “**affiliates**” as used in the Chapter 5, Eligibility Requirements“...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.”

According to Florida law, "State university," ...includes the following institutions and any branch campuses, centers, or other affiliates of the institution..." (s 1000.21 (6), F.S.). Examples of Florida universities and their affiliates include Shands Cancer Center and the University of Florida and the Sylvester Comprehensive Cancer Center and the University of Miami. However the statute also says, "...accept as otherwise specifically provided..." For example, the H. Lee Moffitt Cancer Center and Research Institute was able to show statutory provisions that excluded it from 1000.21(6). In the interest of fairness, eligible non-public institutions have the same restriction applied to them. If it can be legally shown that a branch campus, institute or center is separate and distinct, an exception may be made. If you have a question about your institution's independence, this must be submitted as a question in writing during the question and answer period (see Chapter 9 for dates).

5. Can a Principal Investigator submit the same Shared Instrument Grant application to both the Bankhead-Coley Program and the James and Esther King Program?

No, applicants may not submit duplicate applications or applications for projects with significant scientific, commitment, or financial overlap to both the Bankhead-Coley

Cancer Research Program and the James & Esther King Biomedical Research Program. The Principal Investigator may submit completely different applications for different instruments to the two programs. The Principal Investigator must decide which program is a better fit for his/her project.

6. Can a Principal Investigator submit two different applications to the Bankhead-Coley Program and the James and Esther King Program?

The Principal Investigator may submit different applications to the Bankhead-Coley Cancer Research Program and the James & Esther King Biomedical Research Program, as long as there is no scientific, commitment, or financial overlap between the projects. The PI can receive funding from both programs for completely different projects.

7. It is my understanding that the tobacco-relatedness is an absolute requirement; however, I have had several questions as to the exact interpretation of "tobacco-relatedness." Is this to be understood as having "ongoing funded tobacco-related research projects?" or does it mean doing research that "might lead to therapies that could be used in the treatment of tobacco-related diseases" or anything in between?

The Program is interested in funding projects with the greatest potential to lead to the prevention, diagnosis, treatment, and/or cure of tobacco-related diseases, and recognizes that cures will require a multidisciplinary approach. Consequently, for this Call for Grant Applications, tobacco-relatedness may be broadly interpreted; however, a major part of the application evaluation criteria is the alignment of the proposed projects to tobacco-related diseases. This relationship will be judged as part of the peer review process, and may be used in the final funding recommendations. Proposed projects that do not or cannot demonstrate tobacco-relatedness will not be funded.

8. Normally, in my experience with electronic submissions, the agencies require that the authorized official and the institution register in order to be notified when a proposal is ready for approval (if required by the agency). As the authorized official that signs grants and contracts for the [institution], do I need to register myself and/or [my institution] for these grant programs?

No, only one registration is required for each application; this is normally the Principal Investigator. Certain sections of the application require the Principal Investigator to download and complete forms that must be signed by the Authorizing and/or Administrative Official(s) before being uploaded into the online application. Examples include the cover/certification page and the budget form.

9. I understand that an institution can only submit three Shared Instrument Grant applications. Are there any stipulations about whether one investigator's projects can be listed on more than one of those grant submissions? For example, can Joe Smith and his grants totaling \$400,000 in funding be listed as a project on two or all three of the Shared Instrument Grant submissions?

Yes, the same investigator's projects may be included on multiple Shared Instrument Grant applications; however, the applicant must present a convincing case that all instrument requests are relevant and necessary to support the project(s) in question.

10. Can I apply for a shared instrument that costs more than \$500,000 as long as my institution can come up with the amount exceeding the \$500,000 from other institutional sources?

Yes. The amount and source of additional funds should be addressed within the application and confirmed in the institutional letter of commitment.

11. In the Technical Description of Research and Case Supporting the Need for the Equipment section -- do I have to cut and paste in appropriate boxes or I can upload a PDF file? If I have to paste, can I include a schematic of experimental set-up figures?

You can either type directly into this section or cut and paste information from another document, but keep in mind that special characters or diagrams will not be converted or displayed. You will not be able to upload documents into this section nor post a schematic. If you believe a schematic or diagram is essential to understanding the physical configuration of the equipment, include it in the Vendor Itemized Quote PDF file; however, you may not bypass page limitations imposed on certain sections of the application by including that information in other sections of the application. The Program reserves the right to remove extraneous information from the application before it undergoes peer review.

12. I want to clarify that the PI of the Grant can be the Principal Investigator on one of the 3 representative projects.

Yes, the Principal Investigator of the Grant can also be the Principal Investigator for one of the three or more representative projects.

13. Must all users be funded for tobacco-related research? Must all users be conducting tobacco-related research?

At least 75% of the total usage of the instrument(s) must be for tobacco-related research projects. It is not necessary for all three of the major user groups listed in the application to have already been funded for tobacco-related research; however, the applicant must show how obtaining the instrument will further the prevention, treatment, diagnosis, or cures of tobacco-related diseases. A significant part of the evaluation criteria used in awarding projects is the strength of the tobacco relationship presented in the application.

14. Our institution is planning to submit 3 proposals as allowed. If I am a Principal Investigator of proposal #1, can I be a Principal Investigator of a representative project for Proposal #2 or #3?

Yes, as long as there is no funding or scientific overlap, a PI of Shared Instrument Grant proposal #1 can also be a PI of one of the representative projects listed for any of the Shared Instrument Grant proposals.

15. Regarding the 75% total usage requirement (Chapter 5 C), can the remaining 25% be used for non-tobacco-related projects?

Yes.

16. What are the numbers of awards that will be made?

There is no predetermined number of grants. The quality of the proposals, tobacco-relatedness, and the amount of available funding are considerations used in making award decisions.

ADDENDUM 1 – INSTRUCTIONS FOR SHARED INSTRUMENT GRANT APPLICATIONS

The detailed instructions for the Shared Instrument Grant Application are accessible by clicking on the link below and are also available within the online Shared Instrument Grant application.

[Shared Instrument Grant Instructions](#)