



**Open Call for Grant Applications:
Technology Transfer/Commercialization Partnership
(TTCP) Grant
for Tobacco-Related Diseases
August 10, 2009 – January 29, 2010**

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



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Open Call for Grant Applications: TTCP Grant, August 10, 2009 – January 29, 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, including this Call. This is an Open Call for Grant Applications. Applications will be accepted from August 10, 2009 through January 29, 2010. The next Open Call for TTCP Grant Applications is anticipated to open on or around February 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 **Technology Transfer/Commercialization Partnership Grant** (hereafter referred to as "TTCP Grant") applications from eligible institutions and small businesses 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) Grants
2. Shared Instrument Grants (SIG)

This Call for Grant Applications applies only to TTCP Grant applications. To access the SIG and Florida RC1 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](http://www.floridabiomed.com/jek_call) (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 schedule of deliverables.

2. HIGHLIGHTS

- Each grant mechanism has its own call for applications and instructions documents.
- Small businesses in Florida are eligible to apply for this grant for the first time.
- A partnership between an eligible small business and an eligible institution is required, with both the small business and the eligible institution contributing a minimum of 30% of the required effort. See Chapter 5.
- The TTCP Call is meant to be an open call for applications. This Call for Grant Applications will remain open through January 29, 2010 or until all funding set aside for this mechanism is awarded. A new Call for TTCP Grant Applications in anticipation of FY 2010-11 funding is scheduled to open the following business day (February 1, 2010).
- In accord with the NIH, financial conflict of interest requirements have been relaxed in the Terms and Conditions for TTCP Grants.
- Grants will be awarded on an ongoing basis, based on the peer review scores and the availability of funds. The minimum fundable scores are: 2.2 out of 5.0 for merit and 2.5 out of 5.0 for tobacco-relatedness. Unfunded projects are allowed one resubmission. Up to \$1 million per year has been set aside for TTCP grants. See Chapter 11.
- A link to the peer reviewer questions has been added to Chapter 10.
- 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 use and the proposed project will not be funded.

4. TTCP GRANT MECHANISM INFORMATION

The intent of the TTCP grant mechanism is to: encourage the collaboration of investigators at eligible institutions and small businesses; stimulate technology transfer activities for promising research discoveries that could lead to innovations in the prevention, diagnosis, treatment, or cure of tobacco-related diseases; and strengthen a project's economic feasibility and commercialization prospects. It is not the intent of the Program to replicate or replace funding from other traditional sources such as the National Institutes of Health, but rather to provide funding to fill gaps left by those traditional sources. It is incumbent upon the applicant to clearly show why funding from other sources is not available for the proposed project.

Although preliminary data are not required, proposals must address the feasibility of the project. Collaboration between a small business and an eligible institution is also required.

Projects appropriate for this grant mechanism may include, but are not limited to:

- Generating preliminary data and establishing the technical/scientific merit and feasibility of the project in order to become competitive for future SBIR/STTR federal funding
- Developing and/or improving biomedical equipment useful in the diagnosis, treatment, or cure of tobacco-related disease(s)
- Developing and/or improving assays useful in the diagnosis, treatment, or cure of tobacco-related disease(s)
- Developing new therapies and drugs for tobacco-related disease(s)
- Developing new therapies and drugs useful in smoking cessation treatment
- Developing methods, materials, models, or simulations necessary for translating research findings into standard practices for the prevention, diagnosis, treatment, or cure of tobacco-related disease(s)

A. Application and Award Timeline

1. The intent for the TTCP is to have an open, ongoing Call for Grant Applications. In order to deal with administrative limitations, a new Call for TTCP Grant Applications will be opened each year. Applications will be accepted on a continuous basis.
2. There will be a finite amount of funds set aside for TTCP grants each year. Grants will be awarded until available funds are exhausted. All applications that are fundable but unfunded due to budgetary constraints will be carried forward for up to one year and will be awarded if funds become available. For FY 2009-10, \$1 million has been set aside for TTCP Grants.
3. Notification of awards will be announced within 60 days of application submission.

B. Award Amount and Duration

1. The maximum award is \$100,000 in total costs (including direct and indirect costs).
2. Awards are for a period of 12 months.
3. TTCP grant start dates are dependant on the date of award notification, and will generally begin on the first day of the month following award notification.
4. TTCP grants are not eligible for subsequent 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 projects/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 or an eligible small business (see the definitions provided in Chapter 15).

An **eligible small business** for the purposes of this program must have a place of business in Florida and meet all of the following criteria at the time of application:

- Is a "business entity" as defined in s. 606.03(1), *F.S.* to include any form of corporation, partnership, association, cooperative, joint venture, business trust, or sole proprietorship that conducts business in Florida;
- Is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned, by U.S. citizens or lawfully admitted permanent resident aliens; and

- Is a “small business” as defined by s. 288.703, *F.S.* with less than 200 employees and a net worth of not more than \$5 million (see “small business” definition 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. 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. 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 must involve a **partnership** between at least one eligible institution and at least one eligible small business. Either partner may serve as the applicant organization (applicant), and each partner shall contribute a minimum of 30% of the effort required to complete the proposed project. There must be at least one key person (including the Principal Investigator) at the eligible institution and at the eligible small business.

The sponsoring entity, 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, 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 Chapter 15.

To be eligible as a **Principal Investigator at an eligible small business**, the individual must have his/her primary employment (at least 50% of the individual's time and effort) with an eligible small business at the time of award and throughout the grant period. If the Principal Investigator at the eligible small business is employed for less than 100% effort at the small business, he/she must disclose within the application any other employment.

C. Additional Application Requirements and Limits

Previous recipients of James and Esther King Program Small Business Technology Transfer (SBTT) or TTCP Grants are only eligible to reapply for this grant mechanism for significantly different projects. The Program shall make the final determination as to whether the proposal is unique.

Previously submitted but unfunded James and Esther King or Bankhead-Coley SBTT or TTCP applications can be resubmitted only one time.

Partner Letters of Support from the partnering eligible institution and small business must be provided. The small business partner letter must include: a description of the relationship, role, and contribution that it will make to the proposed project; a statement of intent to collaborate with the eligible partner institution organization; its type of business entity as defined in s. 606.03(1), *F.S.*, the entity's Federal Entity Identification Number (FEIN) or, in place of that, a Dun and Bradstreet (DUNS) number; and an attestation that it meets the small business criteria for eligibility at the time of application. The institution letter must describe the relationship, role, and contribution to the proposed project that it will make and include a statement of intent to collaborate with the eligible small business organization.

Applicants must ensure that their proposed project does not duplicate or significantly **overlap**, scientifically or financially, with other 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, the small business and the institutional partner shall enter into an agreement regarding the allocation of intellectual property rights that is consistent with the provisions of federal STTR programs. A copy of the agreement must be provided to the Program at the end of the first quarter of the grant period.

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 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, patents received, et cetera.

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 Direct Costs

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

- salaries
- fringe benefits
- supplies
- equipment
- domestic travel
- consultant costs
- patient-care costs
- Department of Health IRB fees (if applicable)
- consortium or contractual costs

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.

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 1 annual salary rate of the Federal Executive Pay Scale that is in effect as of September 18, 2009. See Chapter 15, 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 institution. This provision is consistent with the NIH salary limitations on grants, cooperative agreements, and contracts.

It is the intent of the Program that activities funded through the Program, including data analysis, occur in Florida. Eighty percent of work (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. Allowed Indirect Costs

Indirect costs (also referred to as IDC, F&A, or administrative costs) are limited to 10% of the direct costs requested. Indirect costs are those costs that are incurred for the joint or common benefit of several separate organizational or financial components (cost centers) of an organization, which specifically or readily cannot be identified to a particular cost center, project, or program.

C. Disallowed Costs

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

- Construction, renovation, or remodeling
- International travel
- Vehicles
- Entertainment
- Employment subsidies
- Dues/Membership fees
- Meals/Food (other than as part of travel costs)
- Malpractice insurance premiums

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 TTCP GRANT APPLICATION COMPONENTS

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

TOTAL MAXIMUM PAGE LIMIT: 75 printed pages

TOTAL MAXIMUM UPLOADED FILE SIZE: 3 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. TTCP Grant Application Components and Page Limits			
Section	Category	Page Limit	Comment
General Project Information*:			
A	General Project Information	2	Required. This section includes general project information.
B	General Audience Abstract	1500 characters	Required. This section will explain the proposed project in layman's 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	Key Personnel	1	Required. This section identifies all key personnel.
E	Tobacco-Relatedness	3000 characters	Required. This section should provide a clear explanation of how the technology transfer/commercialization project is related to tobacco use or tobacco-related diseases.
F	Small Business Information	1	Required. This section requests information regarding the small business and work effort to be performed by the eligible institution and small business.

Table 1. TTCP Grant Application Components and Page Limits			
Section	Category	Page Limit	Comment
Main Application Body**:			
G	Table of Contents	1	Required.
H	Alternative Funding Challenges		Required. This section should provide a clear explanation of why funding from other sources is not available for the proposed project.
I	Resources	2	Required.
J	Research/Project Plan	12	Required.
K	Partner Information	4	Required. This section requests information regarding the related experience and capabilities of each of the partner organizations to support their respective roles in the proposed project.
L	Literature Cited	3	Required.
M	Human Subjects	No limit	Required if applicable.
N	Vertebrate Animals	No limit	Required if applicable.
O	Consultants	2	Required if applicable.
P	Publications, including accepted or submitted manuscripts	10	Optional.
Q	Survey Instruments	No limit	Optional.
Other Documents:			
R	Partner Letters of Support	4	Required. Scanned copies of the original signed Partner Letters of Support from the partnering eligible institution and small business
S	Miscellaneous Letters of Support	4	Optional. Applicants may include letters of support from technology transfer officials and/or potential commercialization partners.

Table 1. TTCP Grant Application Components and Page Limits			
Section	Category	Page Limit	Comment
T	Certificate of Status or Authorization from Division of Corporations, Florida Secretary of State; or any other certifications from the Secretary of State resulting from the requirements of Title XXXVI, Business Organizations, <i>F.S.</i> ; or in place of either of those above, a county business license	No Limit	Required.
U	Biographical Sketches	4 per person	Required for the Principal Investigator, the project leader at the partnering entity, and any other key personnel.
V	Budget	4	Required. The budget must explain the planned spending for the proposed work.
W	Research/Project Milestone Chart	2	Required. The Research/Project Milestone Chart provides a high-level overview of the project schedule.
X	Other Support	No Limit	Required. A report of all other active and pending awards for the principal investigator and the project leader at the partnering entity.
Y	IRB and/or IACUC Approvals	No limit	You may submit an application without necessary IRB or IACUC approvals. Immediately after award notification, grantees should submit all necessary applications to regulatory authorities including, but not limited to, the IACUC, local or institutional IRB, and if necessary, the DOH IRB. Project work may not begin until all approvals are provided. <u>Project name on approvals must match the application project name.</u>

Table 1. TTCP Grant Application Components and Page Limits			
Section	Category	Page Limit	Comment
Z	Cover/Certification Page – Signed	1	Required. The Original signed cover page must be delivered separately by mail no more than 2 days after the application is submitted. A PDF copy of the signed cover/certification page that was mailed to DOH must be uploaded.
TOTAL MAXIMUM PAGE LIMIT: 75 printed pages			
TOTAL MAXIMUM UPLOADED FILE SIZE: 3 MB			
<p>* (Sections A-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 that 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.</u> If this is the case, DO NOT place such information in the <u>General Research Information sections of the application.</u> These sections are subject to publication and wide dissemination in the event you are awarded a grant.</p>			
<p>** (Sections G-Q) 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 ANY TIME AFTER THE CALL IS OPENED	E-mail questions to: questions@floridabiomed.com
Answers posted to written questions	Updates will be made frequently to the website. One question and answer web document will be used as long as the TTCP mechanism is offered.	Find questions and answers at http://floridabiomed.com/king_qa.html
Online applications due	APPLICATIONS MAY BE SUBMITTED ANY TIME AFTER THE CALL IS OPENED	Online applications must be submitted through www.floridabiomed.com
Original signed cover/certification page due	COVER/CERTIFICATION PAGES MUST BE POSTMARKED ON OR BEFORE THE DAY THE APPLICATION IS SUBMITTED FOR RECEIPT BY THE PROGRAM NO LATER THAN TWO BUSINESS DAYS AFTER SUBMISSION	Send signed cover/certification page(s) to the Biomedical Research Programs, Florida Department of Health address listed in Chapter 14 C.
Proposal evaluation summaries available to applicants online	The Principal Investigator will be notified when the evaluation report is available.	Whether or not funding is awarded, the evaluation report will be available to the Principal Investigator by logging in at www.floridabiomed.com .
Awards announced	Within 60 days of application submission until funds are no longer available.	Award letters will be mailed to the signing authority and the Principal Investigator will receive notification by e-mail.

Table 2. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
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, local or institutional IRB, and if necessary the DOH IRB. Project work may not begin until all approvals are provided.	Send scanned signed approvals to: programsupport@floridabiomed.com Note: The project name on the approvals must match the application project name. Refer to Chapter 15 for the DOH IRB definition to determine if approval is required for your project. Visit www.flpublichealthethics.net for DOH IRB instructions and forms.
Grants begin	The first day of a month dependent on application submission.	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.

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.

Answers to questions will be available on the Program website, www.floridabiomed.com. 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)

The Department recommends that applications be submitted as soon as possible to ensure that funding is still available.

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 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.

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, 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. These panels 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 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). Qualified/eligible applications will be assigned to five independent peer reviewers. At least two of the reviewers will have experience with commercialization and business plans and at least two of the reviewers will have expertise in the appropriate science. 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 the other reviewers assigned to the same application, and will not be able to see applications or critiques assigned to other reviewers. Peer reviews will be finished within 60 days after application submission, 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 TTCP proposals for (1) scientific merit (2) business/commercial feasibility on the following criteria:

- Scientific and technical merit of the proposed project
- Feasibility of the work plan and planned approach
- Understanding and milestones leading to a clearly defined next step in the development and commercialization pipeline
- Qualifications of the Principal Investigator to lead the proposed project
- Suitability of the proposed small business/established research institution partnership
- Available resources and environment
- Relationship of the project to the advancement toward prevention, diagnosis, treatment, and cure of tobacco-related diseases
- The anticipated commercial value and/or societal benefits of products, processes, methods, training materials, or services under consideration
- Reasonableness of the case made that a funding gap from traditional sources exists
- Likelihood that the outcome of the project will lead to follow-on funding, such as a federal SBIR/STTR grant or private investment

Reviewers will identify concerns regarding:

- Projects related to human subjects
- Projects related to vertebrate animal subjects
- The proposed budget
- Apparent scientific or budgetary overlap with active or pending support

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

12. NOTIFICATION OF FUNDING DECISION

Applicant entities 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.

Applications that are not fundable due to ineligibility, disqualification, tobacco-relatedness, or scientific merit score may be revised and resubmitted one time.

For this Open Call for TTCP Grant Applications, the Program intends to allocate up to \$1 million and award all fundable applications until funds are no longer available. The Program reserves the right to change the allocated amount. Fundable applications will meet three basic criteria:

- are both eligible and qualified based on the Administrative Review;
- received a Merit Review score of 2.2 or better on a scale of 1 to 5, with 1.0 representing the highest possible rating; and
- received a Tobacco-Relatedness Merit Score of 2.5 or better on a scale of 1 to 5, with 1.0 representing the highest possible rating

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 the 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 and availability of funds, the application will be classified either as funded, fundable but unfunded, or unfundable. Note that while a reconsideration may lead to funding, it could also result in a lower ranking. 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 and in the specified format 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, 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 at the same time the application is uploaded to GrantEase. **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 contractual agreements, budgets, and letters of support, 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 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.

D. Online Application Submission

To complete the online application process:

1. Register as an applicant on <http://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 <http://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 and the Scientific Abstract, 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-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 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. 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.**

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. The scientific and technical merit of the proposed project is the primary concern for peer evaluation.
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.

7. Before it can be submitted, the application must contain all of the required sections identified in Table 1. Use the Table of Contents to ensure that a complete application is submitted. 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

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 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 entity. 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.

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.

DOH IRB: DOH IRB refers to the Institutional Review Board operated by the Florida Department of Health Office of Public Health Research. It is independent from any IRB that may have jurisdiction over research performed at the Grantee institution. Per the “Department of Health, Institutional Review Board, Activities Subject to IRB Jurisdiction” policy DOHP 400-1.2, studies funded by the James and Esther King Biomedical Research Program and the Bankhead-Coley Cancer Research Program do NOT require review by the DOH IRB unless the research involves Department of Health clients, personnel, facilities, or data. Note: an application for DOH IRB approval (if applicable) is not required to be submitted until after a project has been awarded. Visit www.flpublichealthethics.net for DOH IRB instructions and forms.

Eligible Institution: Any public university, non-public institution, or established research institute (see specific definitions of each).

Eligible Small Business: Any entity with a principal site in Florida meeting all of the following criteria at the time of application:

- Is a "Business entity" as defined in s. 606.03(1), *F.S.* to include any form of corporation, partnership, association, cooperative, joint venture, business trust, or sole proprietorship that conducts business in Florida;
- Is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned, by U.S. citizens or lawfully admitted permanent resident aliens; and
- Is a “small business” as defined by s. 288.703, *F.S.* with less than 200 employees and a net worth of not more than \$5 million.

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.

Federal Executive Pay Scale, Executive Level 1: 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 1 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 75% of the contracted services for the fiscal year. This includes tenured, tenure-track, and non-tenure track appointments.

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.

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. For TTCP applications, there must be at least one key personnel at both the eligible institution and the eligible small business.

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 the Principal Investigator and project leader of the partnering entity, 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.

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.

Small Business: Per s. 288.703(1), F.S., a "small business" means an independently owned and operated business entity that employs 200 or fewer permanent full-time employees and that, together with its affiliates, has a net worth of less than \$5 million; or any firm based in Florida that has a Small Business Administration 8(a) certification¹ as applicable to sole proprietorships. The \$5 million net worth requirement shall include both personal and business investments.

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 to 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. What is the budget limit for equipment and supplies?

There is no specific dollar limit for purchasing equipment or supplies. You should identify and justify equipment and supplies in the budget. Excessive equipment and supplies budgets will be scrutinized.

5. Regarding the budget form, what is the difference between percent effort and percent salary?

The percent effort on a project is the amount of an individual's time (some percentage between 1 and 100) that is spent on this project. Percent salary is the percent of the person's salary that is funded by this project. For example, an individual could work 50% of his/her time on a project but only request funds for 40% of his/her salary. Most often these two numbers are the same.

¹ § 124.101 What are the basic requirements a concern must meet for the 8(a) BD program?

Generally, a concern meets the basic requirements for admission to the 8(a) BD program if it is a small business which is unconditionally owned and controlled by one or more socially and economically disadvantaged individuals who are of good character and citizens of the United States, and which demonstrates potential for success.

6. Regarding “all financial resources” in Other Support – does this include institutional support funds received in the recruitment package for the Principal Investigator?

Yes, recruitment packages are reportable as “other support.”

7. Does the Program solely fund biomedical research or does it also fund projects pertaining to motivational and behavior problems relevant to tobacco use without any biomedical component?

Refer to Chapter 3 Tobacco-Relatedness, which addresses behavioral research proposals. Motivational and behavioral research proposals related to tobacco use or tobacco-related diseases are appropriate and encouraged.

8. Can a Principal Investigator submit the same project 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 to the two programs. The Principal Investigator must decide which program is a better fit for his/her project.

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

The Principal Investigator may submit different applications to 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.

10. 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 this 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 project to tobacco-related diseases. This relationship will be judged as part of the peer review process, and will be used in the final funding recommendations. Proposed projects that do not or cannot demonstrate tobacco-relatedness will not be funded.

11. 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.

12. Are IRB or IACUC approvals needed before the application deadline, or can I submit them later?

The IRB approval is not required before the application deadline. You may submit an application without the necessary IRB or IACUC approvals. Immediately after award notification, grantees must submit all necessary applications to regulatory authorities including, but not limited to, the IACUC, local or institutional IRB, and if necessary the DOH IRB. Project work may not begin until all approvals are obtained. To determine if you will need to obtain the DOH IRB approval, please review the definition of DOH IRB in Chapter 15, Definitions.

13. What are the numbers of awards that will be made? How many of each type of award were given in past years?

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 TTCP GRANT APPLICATIONS

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

[TTCP Instructions](#)