



**Call for Grant Applications:  
Biomedical, Biotechnological, and Social  
Scientific Research and Development  
Fiscal Year 2009-2010**

**Bridge Grant  
New Investigator Research Grant  
Team Science Program Grant  
Technology Transfer/Commercialization Partnership Grant**

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



**Issued: December 1, 2008**

**TABLE OF CONTENTS**

**James and Esther King Biomedical Research Program  
Call for Grant Applications – FY 2009-2010**

Synopsis of Major Changes.....	3
<b>1. Introduction .....</b>	<b>4</b>
<b>2. Grant-Making Process Overview.....</b>	<b>6</b>
<b>3. Tobacco-Relatedness .....</b>	<b>7</b>
<b>4. Global Eligibility Requirements.....</b>	<b>7</b>
<b>5. Allowed and Disallowed Costs.....</b>	<b>8</b>
<b>6. Online Application Registration .....</b>	<b>10</b>
<b>7. Bridge Grant .....</b>	<b>10</b>
A. Bridge Grant Award Amount and Duration.....	11
B. Specific Bridge Grant Eligibility Requirements .....	11
C. Required Bridge Grant Application Components .....	12
<b>8. New Investigator Research (NIR) Grant.....</b>	<b>14</b>
A. NIR Award Amount and Duration.....	14
B. Specific NIR Eligibility Requirements .....	14
C. Required NIR Application Components.....	16
<b>9. Team Science Program (TSP) Grant.....</b>	<b>19</b>
A. TSP Award Amounts and Duration .....	20
B. Specific TSP Eligibility Requirements .....	20
C. Required TSP Application Components.....	22
<b>10. Technology Transfer/Commercialization Partnership (TTCP) Grant .....</b>	<b>25</b>
A. TTCP Award Amount and Duration .....	25
B. Specific TTCP Eligibility Requirements .....	25
C. Required TTCP Application Components.....	26
<b>11. Schedule of Important Dates .....</b>	<b>30</b>
<b>12. Inquiries and Contacts.....</b>	<b>31</b>
A. Programmatic Questions About This Call .....	31
B. Technical Questions About the Online Application .....	32
<b>13. Evaluation of Submitted Applications.....</b>	<b>32</b>
A. Administrative Review .....	32
B. Scientific Merit Review .....	33
C. Programmatic Review .....	34
<b>14. Notification of Funding Decision.....</b>	<b>34</b>
<b>15. Requests for Re-Consideration .....</b>	<b>35</b>
<b>16. Instructions for Application Submission.....</b>	<b>35</b>
A. Confidentiality of Submitted Materials.....	36
B. Original Signature Page and Other Materials .....	36
C. Online Application Submission .....	37
D. General Guidelines.....	37
<b>17. Definitions .....</b>	<b>38</b>
<b>18. Frequently Asked Questions.....</b>	<b>42</b>
<b>Addendum 1 – Instructions for Bridge Grant Applications .....</b>	<b>48</b>
<b>Addendum 2 – Instructions for NIR, TSP, and TTCP Grant Applications .....</b>	<b>48</b>

## SYNOPSIS OF MAJOR CHANGES

For convenient reference, the following list describes the significant differences between this *Call for Grant Applications* document and the *2008-2009 Call for Grant Applications* document issued by the James & Esther King Biomedical Research Program.

1. In Chapter 1 and Chapter 16 A, additional information has been added regarding Chapter 119, *F.S.* and public access to submitted material.
2. In Chapter 1, requirements regarding Open Innovation and Sharing of Publication-Related Materials, Data and Software have been added.
3. In Chapter 4, global eligibility requirements have been clarified.
4. In Chapter 5, the indirect cost percent has increased to ten percent.
5. In Chapter 7, the assigned score or rating that signifies “high scientific merit” for Bridge Grants has changed to “2.0 (200) or lower.”
6. In Chapter 8 B, item 5, a clarification has been added for Specific NIR (New Investigator Research) Eligibility Requirements regarding previous grants. A Co-Principal Investigator is defined as an “equally responsible independent investigator.”
7. In Chapter 8 B, item 6, the number of years since the Principal Investigator’s first Full-time Faculty appointment has changed from five years to six years.
8. In Chapter 9 A, item 2, the duration of Team Science Program Grants can be up to 36 months.
9. In Chapter 9 B, item 2, a change has been made to the number of Team Science Program (TSP) Grant applications an institution can submit. An eligible institution may submit one intra-institutional TSP application and one inter-institutional TSP application. TSP related frequently asked questions have been added in Chapter 17.
10. In Chapter 10 and throughout the document where appropriate, the grant mechanism Small Business Technology Transfer Grant (SBTT) has been renamed the Technology Transfer/Commercialization Partnership (TTCP) Grant. This mechanism is offered to support researchers in their efforts to submit federal STTR applications or in developing materials to translate research discoveries into standard practice. In Chapter 10 B, eligible established small business entity has been clarified.
11. In Chapter 17, several definitions have been updated or added for clarification.
12. In Chapter 18, additional frequently asked questions have been added.
13. In Addendum 1, a link to the Bridge Grant application instructions has been added to this document.
14. Addendum 2, a link to the NIR, TSP, and TTCP Grant application instructions has been added to this document.

## 1. INTRODUCTION

In 1999, the Florida Legislature established a Biomedical Research Program, now known as the James and Esther King Biomedical Research Program, to support research for the prevention, diagnosis, treatment, and cure of tobacco-related diseases. Since its inception, program funding has come from the interest earned on a \$150 million reserve within the Lawton Chiles Endowment Fund, a fund established with monies received from the tobacco industry through Florida's tobacco lawsuit settlement agreement (section (s.) 215.5601, *Florida Statutes (F.S.)*). Additionally, in fiscal year 2006-2007 the Florida legislature appropriated \$6 million per year for five years to the Biomedical Research Trust Fund within the Florida Department of Health for purposes of the James and Esther King Biomedical Research Program pursuant to s. 215.5602, *F.S.* From these funds up to \$250,000 shall be available for the operating costs of the Florida Center for Universal Research to Eradicate Disease (FL CURED). The Florida Department of Health, through the Office of Public Health Research (hereafter referred to as "the Department") administers the James and Esther King Biomedical Research Program (hereafter referred to as "the Program") with the support of a contracting partner, Lytmos Group. The Program also solicits recommendations and suggestions on policy alternatives from the Biomedical Research Advisory Council consistent with Chapter 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 **biomedical, biotechnological, and social scientific research and development** applications from Florida-based universities and established research 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.

The Department will accept **biomedical, biotechnological, and social scientific research and development** applications for four grant mechanisms:

1. Bridge Grant
2. New Investigator Research (NIR) Grant

3. Team Science Program (TSP) Grant
4. Technology Transfer/Commercialization Partnership (TTCP) Grant

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

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, and to ensure the protection of human subjects as well as compliance with applicable state and federal laws or regulations.

### **Open Innovation and Sharing of Publication-Related Materials, Data, and Software**

Publishing a scientific paper is a quid pro quo in which authors receive credit and establish priority in exchange for disclosures of their scientific findings. A responsibility of authorship is to make available materials, databases, and software integral to the publication so that others may validate or refute the results and extend them in new directions. Upon publication of their work, grantees funded through this Program are encouraged to make materials, data and databases, and software that result from this funding and which is integral to their publication, freely and expeditiously available upon request for research use by other scientists, utilizing materials transfer agreements.

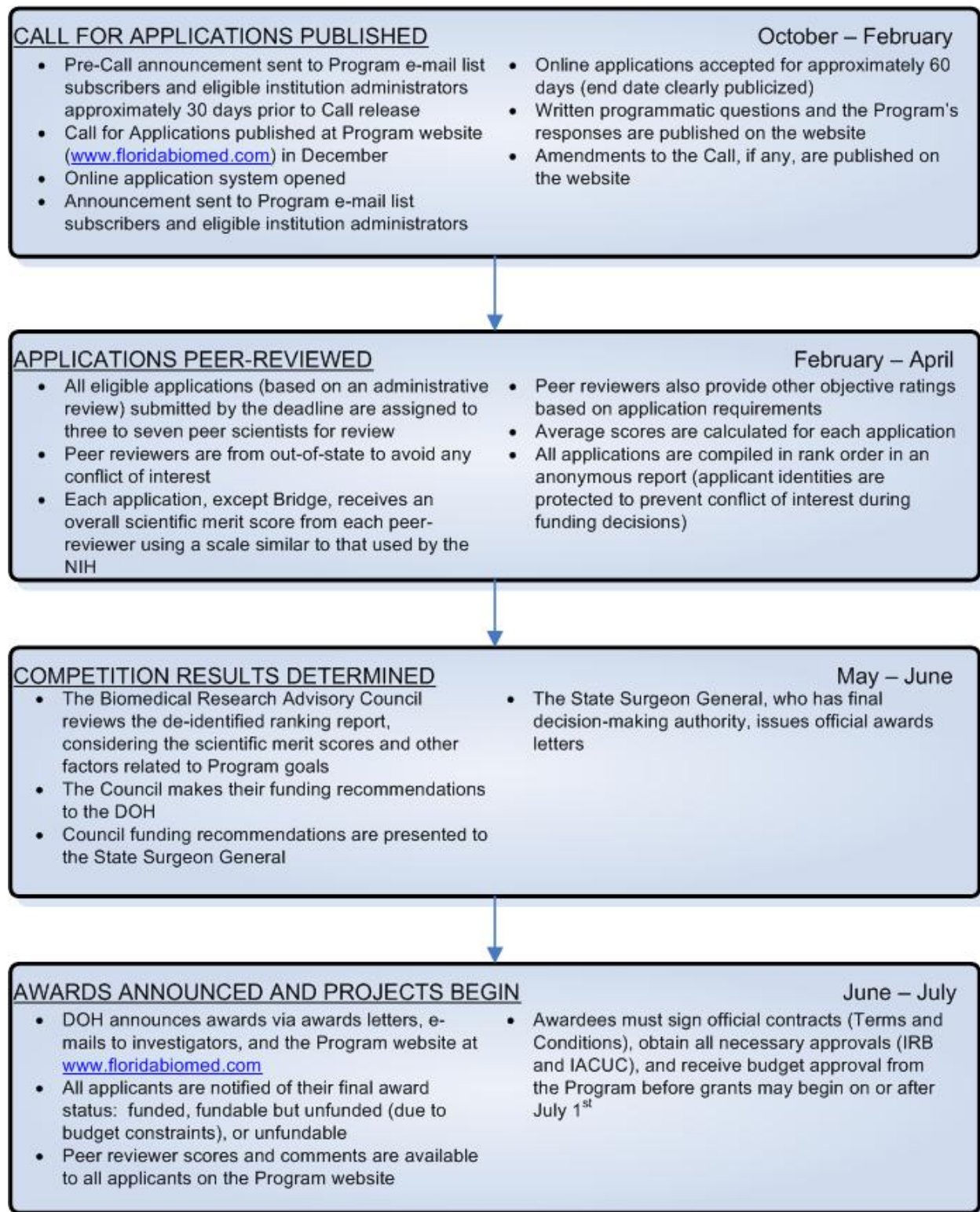
In concert with the National Institutes of Health (NIH) notice NOT-OD-08-033, Grantees shall submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available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

#### ***Important:***

***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](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.***

## 2. GRANT-MAKING PROCESS OVERVIEW



### 3. TOBACCO-RELATEDNESS

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

### 4. GLOBAL ELIGIBILITY REQUIREMENTS

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:

1. 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, center or affiliate, 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.
2. 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.
3. 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.

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 11 for dates).

Public and nonpublic institutions must be accredited by a nationally recognized organization.

The principal site (see definition for "principal site" in Chapter 17) for the project must be within the Florida facilities of an eligible institution or that of an organization collaborating on the project. It is the intent of the Program that research funded through the Program, including data analysis, occurs in Florida at the principal site.

Principal investigators/Project Directors from eligible institutions may apply for funding from the Program. Individual mechanisms may have limitations that modify eligibility so carefully read the specific criteria associated with each. The sponsoring institution, in accordance with its own policies and procedures, should designate the Principal Investigator/Project Director. The Principal Investigator must supervise the research 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/Project Director**, the individual must be a full-time faculty member at an eligible college or university or the equivalent at an eligible research institution, or a postdoctoral researcher in his/her final fellowship year by the application due date of February 13, 2009. Postdoctoral applicants must be a Full-time Faculty member or equivalent by June 1, 2009. Temporary faculty members, even though full-time, are not eligible to apply. See Full-time Faculty and Full-time Equivalent definitions in Chapter 17. In the case of Technology Transfer/Commercialization Partnership (TTCP) Grants, an eligible institution must partner with a small business. (See Chapter 10 for specific TTCP requirements.)

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. The proposed research also must not overlap with any research conducted by the New Investigator Research mentor.

## 5. ALLOWED AND DISALLOWED COSTS

The following information explains direct and indirect costs allowed by the Program, as well as those explicitly disallowed. Additional budget instructions are available online with the application form, which is accessible after you register and login to the online system at [www.floridabiomed.com](http://www.floridabiomed.com). See Chapter 6 for registration instructions.

**Direct Costs:** Allowable 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, and consortium or contractual costs. Note, applicants must register as described in Chapter 6 to access the application and instructions. Administrative costs *may* be included in direct cost categories, but only under two conditions:

- the services, functions, or activities are directly necessary for the conduct of this grant,
- AND
- these administrative costs have not been included in the calculation of the indirect costs.

The **maximum annual institutional base salary** for any personnel named on the application for this grant must not exceed the Executive Level 1 annual salary rate of the Federal Executive Pay Scale that is in effect as of February 13, 2009. See Chapter 17, Definitions, for more information about the Federal Executive Pay Scale. This salary cap is exclusive of fringe benefits, facilities, and administrative (F&A) expenses, and excludes any income that an individual may be permitted to earn outside of the duties to the applicant institution. This provision is consistent with NIH salary limitations on grants, cooperative agreements, and contracts.

All salary caps apply for salary only, and do not include benefits.

The Program does not prohibit administrative 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.

**Indirect Costs:** Indirect costs (also referred to as F&A or administrative costs) are limited to ten percent of the direct costs requested. Administrative or 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.

**Disallowed Costs:** 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

Each type of grant mechanism has additional specific eligibility requirements identified in Chapters 7, 8, 9 and 10. Grant applications that fail to meet all applicable requirements will be rejected.

## 6. ONLINE APPLICATION REGISTRATION

Interested applicants must register online at [www.floridabiomed.com/login.html](http://www.floridabiomed.com/login.html) to submit an application for any of the grant mechanisms outlined in this Call. Data collected during registration includes basic contact information, proposal subject, brief proposal description, and the grant mechanism of interest (Bridge, NIR, TSP, or TTCP). Registered applicants will receive a username and password that will allow access to the online application system. **Only applications received through the Lytmos online application system will be accepted for this Call.** No paper submissions of the grant application will be accepted. See Chapter 16 for application submission instructions and Addendum 1 and 2 for specific field-level instructions.

Application instructions are also included with the online application accessible after registering and logging into the online system at [www.floridabiomed.com](http://www.floridabiomed.com).

## 7. BRIDGE GRANT

The intent of this grant mechanism is to provide interim support for promising tobacco-related investigator-initiated research projects that have been highly rated by national panels of peer reviewers in recent federal competitions but were not funded due to budgetary constraints. Allowable federal competitions include those conducted by the National Institutes of Health, the Department of Defense Congressionally Directed Medical Research Programs, the National Science Foundation, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and the Food and Drug Administration.

To be eligible, applicants must have submitted a multi-year investigator-initiated research application to a federal agency (such as an NIH R type) and have received a peer review summary statement dated on or after February 15, 2008 indicating high scientific merit (referred to as a **“Qualifying Federal Proposal”**). K type career development grants are not eligible. For purposes of this competition, “high scientific merit” is a percentile ranking of 30<sup>th</sup> or better (less) among all scored proposals, or in absence of a percentile ranking an assigned score or rating of 2.0 (200) or lower on a scale of 1.0 to 5.0 (100 to 500), with 1.0 (100) representing the most favorable rating. Projects must be tobacco related, and may involve basic science, translational or clinical research, medical devices, bioinformatics, epidemiology, or human behavior. Proposals must demonstrate a clear relationship between the proposed research and the advancement toward prevention, diagnosis, treatment, and/or cure of tobacco-related disease.

In cases where a summary statement is not yet available, the Program will accept a screen print of one or more funding agency Web page(s) supporting the peer review rating or priority score for the Qualifying Federal Proposal, as long as the following information is clearly contained in the image(s):

- the name of the federal agency (and institute, if applicable)
- a percentile ranking of 30 percent or less (or an assigned score or rating)
- a posting date on or after February 15, 2008

- a proposal title that exactly matches the title provided for the Qualifying Federal Proposal

If a screen print of the Web page(s) is submitted as evidence of qualifying information, the applicant must submit the summary statement to be received no later than May 1, 2009 via e-mail to: [programsupport@floridabiomed.com](mailto:programsupport@floridabiomed.com) and by overnight courier to the Florida Department of Health address located in Chapter 16 B.

If a Bridge Grant is awarded and the grantee is also awarded the highly rated federal grant on which the Bridge Grant is based or is awarded a grant with significant overlap, the Bridge Grant must be relinquished and must terminate no later than the day before the federal grant begins.

### **A. Bridge Grant Award Amount and Duration**

1. Florida investigators at all levels of experience may apply for a one-year Bridge Grant award of up to \$200,000. In no case will the award amount exceed the level of annual project funding originally sought for direct costs in the Qualifying Federal Proposal, plus ten percent indirect costs.
2. Awards are for a period of 12 months and will begin on or about July 1, 2009 and end June 30, 2010.
3. Bridge Grants are not eligible for subsequent non-competitive continuation support.

### **B. Specific Bridge Grant Eligibility Requirements**

In addition to the global eligibility requirements discussed in Chapter 4, the following conditions must be met:

1. The Principal Investigator may submit only one Bridge Grant application.
2. Applicants may not submit duplicate projects or projects with significant scientific or financial overlap to both the Bankhead-Coley Cancer Research Program and the James & Esther King Biomedical Research Program. The Principal Investigator may submit two completely different projects to the two programs, one to each program.
3. Previous Bankhead-Coley or James & Esther King Bridge Grant recipients can not apply for another Bridge Grant for the same research project.
4. If the percent effort of the Principal Investigator to be dedicated to research funded by a Bridge Grant is less than that proposed in the Qualifying Federal Proposal, justification must be provided in the application.
5. Bridge Grant awardees will be required to resubmit a federal proposal directly related to research described in the Qualifying Federal Proposal before June 30, 2010.

## C. Required Bridge Grant Application Components

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

<b>Table 1. Bridge Grant Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
<b>General Research Information:</b>			
A	Cover Page/Certification and General Research Information*	2	Required. <b>Original signed cover page must be delivered separately by due date as specified in Chapter 11.</b>
B	General Audience Abstract from Qualifying Federal Proposal*	3500 characters	Required. This is a general audience or lay abstract from Qualifying Federal Proposal.
C	General Audience Abstract of Proposed Bridge Grant Research*	2000 characters	Required. This section will explain the proposed research in layman's terms, including its relationship to the goals of the Program.
D	Summary of Proposed Bridge Grant Research Plan**	4	Required. This is a brief scientific description of the specific research that will be performed as a result of a Bridge Grant award, including its relationship to the aims and experiments included in the Qualifying Federal Proposal.
<b>Appendices:</b>			
I	Budget	4	Required. The budget will explain the planned spending for the proposed work.
II	Research Milestone Chart	2	Required. The Research Milestone Chart provides a high-level overview of the project schedule.
III	Other Support	No Limit	Required. This is a report of all other active and pending awards for the Principal Investigator.

<b>Table 1. Bridge Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
IV	Documentation of Peer Review Support for Qualifying Federal Proposal	No Limit	Required. Applicants must submit evidence supporting a Qualifying Federal Proposal, including a copy of the actual summary statement response (or screen print) from the federal agency as indicated above.
V	Copy of Qualifying Federal Proposal**	No Limit	Required. A pdf copy of the entire federal proposal as submitted. No additional data will be accepted.
VI	Applicant's Institution 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, IACUC, the DOH IRB (if necessary) and local IRB. Project work may not begin until all required approvals are obtained. <u>Project name on approvals must match the application project name.</u>
VII	PI Biographical Sketch	4	Required for the Principal Investigator.
VIII	Certification – Signed Page 1	1	Required. A pdf copy of the signed certification/cover page of the application that was mailed to DOH.
Proposals exceeding the page limits where specified are subject to truncation to the page limit or may be disqualified without review.			

**Table 1. Bridge Application Components and Page Limitations**

\* (Sections A-C) Submitted materials are subject to the provisions of Art. I, Sec. 24, *Florida Constitution* and Chapter 119, *F.S.*, Florida's public records laws. These laws grant a right to inspect any public record. There are some documents and information which are exempt from the public records laws. 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.

\*\* (Sections D, V) 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.

## 8. NEW INVESTIGATOR RESEARCH (NIR) GRANT

The intent of this grant mechanism is to foster development of new Florida-based investigators so that they can undertake independent research and compete for national research funding. Projects must be conducted under the mentorship of a senior investigator. Proposals must address an important **biomedical, biotechnological, and social scientific research and development problem** relevant to tobacco use or tobacco-related disease. A grant recipient must commit to applying for a follow-on national grant such as an R21, R33, or R01.

### A. NIR Award Amount and Duration

1. The maximum award for NIR grants is \$125,000 per year, not to exceed \$375,000 over three years (including direct and indirect costs).
2. Awards are for a period of up to 36 months and will begin on or about July 1, 2009.
3. Second and third year support for the project are dependent on project performance and subject to the availability of funds. Grantees must submit a request for continuation support at least 60 days before the end of the first and second years. Subsequent annual support shall comply with the same *Terms and Conditions* as the initial award, including any amendments thereof.

### B. Specific NIR Eligibility Requirements

In addition to the global eligibility requirements discussed in Chapter 4, the following conditions must be met:

1. The percent effort of the Principal Investigator must be at least 20 percent full-time equivalent (FTE) each year.
2. The maximum annual salary allowance for a Principal Investigator is \$80,000 per year or 75 percent FTE per year, whichever is less. The percent FTE support requested shall not exceed the actual percent of effort.
3. The maximum amount that a mentor can request for participating in the project is \$25,000 per year. This request may be for salary or for conducting research. If requested for salary, the percent FTE support requested shall not exceed the actual percent of effort.
4. Previous recipients of a James and Esther King NIR Grant are not eligible to apply for another James and Esther King NIR Grant.
5. Previous recipients of the Bankhead-Coley Cancer Research Program two-year Bridge Grant for new investigators or the New Investigator Research Grant may apply for a James and Esther King New Investigator Research grant; however, no scientific or financial overlap is allowed.
6. Previous Project Directors and Principal Investigators on a Bankhead-Coley Cancer Research Program SPORE Planning Grant or a James and Esther King Biomedical Research Program Team Science Program Grant are not eligible to apply for a James and Esther King NIR Grant.
7. The Principal Investigator **must not** have achieved the status of independence defined by successfully competing as a Principal Investigator or Co-Principal Investigator (equally responsible independent investigator) for a non-mentored, peer-reviewed, national grant with a budget of \$100,000 or more per year in direct costs. Examples of national grants include those from the National Institutes of Health, the National Science Foundation, and components of the Department of Defense, as well as national programs offered by the American Cancer Society, the American Heart Association, or the American Lung Association.
8. No more than six (6) years may have passed since the Principal Investigator's first Full-time Faculty appointment at any university or equivalent appointment at a research institution, regardless of location, as of the award activation date. See Full-time Faculty and Full-time Equivalent definitions in Chapter 17. Approved family health leave including, but not limited to, maternity, paternity, or adoption leave exceeding 90 days **will not** count towards the six-year requirement.
9. All applicants must have a mentoring relationship with a senior investigator and will be required to submit a mentoring plan as part of the application. The mentor is an important resource and educator for a new investigator. The role of the mentor is to provide guidance, support, and experience to the Principal Investigator. The mentor should provide scientific advice, grant experience, project management guidance, and lab management counsel related to the project. Furthermore, the mentor should provide general guidance related to fostering development of the new investigator so that they can undertake independent research that is competitive for national research funding. The mentor can be from the same or different institution as the Principal Investigator.

10. All applications must include a Department Head/Chair Letter of Assurance.
11. Applicants may submit only one James & Esther King Program NIR application.
12. Applicants may not submit duplicate projects or projects with significant scientific or financial overlap to both the Bankhead-Coley Cancer Research Program and the James & Esther King Biomedical Research Program. The Principal Investigator may submit two completely different projects to the two programs, one to each program.

### C. Required NIR Application Components

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

<b>Table 2. NIR Grant Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
<b>General Research Information*:</b>			
A	Cover Page/Certification and General Research Information	2	Required <b>Original signed cover page must be delivered separately by due date as specified in Chapter 11.</b>
B	Project Summary	1500 characters	Required. This section should provide a general audience project summary.
C	Scientific Abstract	2000 characters	Required. This is the scientific description of the research.
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 research is related to tobacco-related diseases.
<b>Main Application Body**:</b>			
F	Table of Contents	1	Required
G	Resources	2	Required
H	Research Plan	20	Required
I	Literature Cited	6	Required
J	Human Subjects	No limit	Required if applicable
K	Vertebrate Animals	No limit	Required if applicable

<b>Table 2. NIR Grant Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
L	Consortium/Contractual Agreements	2	Required if applicable
M	Consultants	2	Required if applicable
N	Department Head/Chair Letter of Assurance	2	Required. A scanned copy of the original signed Letter of Assurance must be included in the application.
O	Biographical Sketch(es)	4 per person	Required for all key personnel, including the Mentor.
P	Miscellaneous Letters of Support	No limit	Optional
Q	Publications, including accepted or submitted manuscripts	10	Optional
R	Survey Instruments	No limit	Optional
<b>Appendices:</b>			
I	Budget	4	Required. The budget will explain the planned spending for the proposed work.
II	Research Milestone Chart	4	Required. The Research Milestone Chart provides a high-level overview of the project schedule.
III	Other Support	No Limit	Required. This is a report of all other active and pending awards for all key personnel.
IV	Mentorship Plan	3	Required. The mentorship plan must be signed by the Principal Investigator and Mentor. This plan describes the nature and frequency of intended interaction.

<b>Table 2. NIR Grant Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
V	Applicant's Institution IRB or IACUC Approvals	No limit	You may submit an application without necessary IRB and/or IACUC approvals. Immediately after award notification grantees should submit all necessary applications to regulatory authorities including, but not limited to, IACUC, the DOH IRB and local IRB. Project work may not begin until all approvals are obtained. <u>Project name on approvals must match the application project name.</u>
VI	Certification – Signed Page 1	1	Required. A pdf copy of the signed certification/cover page of the application that was mailed to DOH.
<p><b>TOTAL MAXIMUM PAGE LIMIT: 75 printed pages</b></p> <p><b>TOTAL MAXIMUM UPLOADED FILE SIZE: 3 MB</b></p> <p>Includes cover page and all required and optional sections (including Appendices). Proposals exceeding the total maximum page limits are subject to truncation to the page limit or may be disqualified without review.</p>			
<p>* (Sections A-E) 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>** (Sections F-R) 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. TEAM SCIENCE PROGRAM (TSP) GRANT

The intent of this grant mechanism is to support a broadly based, often multi-disciplinary research project with a well-defined major objective or theme addressing the prevention, diagnosis, treatment, and/or cure of tobacco-related disease in order to stimulate applications to, and make Florida institutions competitive for high-level federal grants such as Program Project (P-01) awards or Research Center (P-30) awards offered by the National Institutes of Health. Grantees must commit to applying for a follow-on program project (P-01), a research center (P-30) or a multi-investigator R-01 national grant by the end of their TSP Grant.

A TSP project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of the overall objective. A TSP project can be within a single eligible institution (intra-institutional) or can involve more than one eligible institution (inter-institutional). Whether an application is considered intra or inter-institutional is based upon the match requirement. In cases where a researcher from another institution is participating on the project, if only the project director's institution is providing the match, then this is considered an intra-institutional project. For a project to be considered inter-institutional, two or more institutions must contribute to the match.

The TSP project consists of **at least three and no more than five** interrelated individual research projects led by a Project Director. The Project Director must be a recognized senior investigator and is expected to define the integrating theme and to develop the approaches that will be used to accomplish the objective(s) of the proposed research program. The Project Director must be a full-time employee of the submitting eligible institution.

A Principal Investigator must lead each individual research project within the TSP. These projects should demonstrate an essential element of unity and interdependence, i.e., a set of research activities and projects directed toward a well-defined research TSP project goal. The important concept that distinguishes a TSP project from a collection of individual projects is the demonstrated synergy between the investigators, shared research resources, and shared research goals. A TSP project must be seen as greater than the sum of its parts.

The award can support individual research projects within the TSP project as well as core facilities and services essential for collaborative investigations. Individual research projects supported by a TSP grant must relate to the overall theme and goals of the TSP project. Applicants (Project Director and all Principal Investigators) must ensure that their proposed project does not duplicate or significantly overlap the financial support of other research projects where they are the Principal Investigator or Co-Investigator. Support for individual projects is contingent upon demonstrating how the supported project enhances collaborative investigations in support of the overall theme of the TSP project. However, not all individual research projects within the TSP project need to be financially supported directly by the TSP grant. A TSP award can support certain common resources used by the research team. Such resources should be used by two or more projects within the TSP. Development of critical research infrastructure may be an appropriate use of funds. However, applicants should keep in mind that it is incumbent upon them to show how acquisition of such equipment will strengthen a federal grant application.

TSP applications must include the following:

- A TSP project narrative that explicitly presents the goals and significance of the overall project
- A programmatic theme that coordinates and integrates the individual research projects
- A demonstration of coordination, interrelationships, and synergy among the research projects
- Descriptions of the individual research projects
- Descriptions of core facilities and services and how they will contribute to collaborative research among the individual research projects
- A description of the planning efforts and an explanation of how these will contribute to the development of a strong application for federal funding

### **A. TSP Award Amounts and Duration**

1. The maximum award for TSP grants is \$500,000 per year, not to exceed \$1,000,000 over two or three years (including direct and indirect costs).
2. Awards are for a period of up to 36 months and will begin on or about July 1, 2009.
3. Second (and third) year support for the same research project are dependent on project performance and subject to the availability of funds. Grantees must submit a request for continuation support at least 60 days before the end of the first (and second) year(s). Subsequent annual support shall comply with the same *Terms and Conditions* as the initial award, including any amendments thereof.

### **B. Specific TSP Eligibility Requirements**

In addition to the global eligibility requirements discussed in Chapter 4, the following conditions must be met:

1. An eligible institution<sup>1</sup> may submit a maximum of two applications for a TSP Grant:
  - a. **One** application for an **intra-institutional** (single institution meeting the required match) TSP Grant. Key personnel may be from other than the applicant institution.

Multiple intra-institutional submissions from the same institution will result in the rejection of all intra-institutional TSP applications from that institution until clarification is received regarding which one application shall be the sole submission for this funding cycle. The Program will correspond with the parties involved via

---

<sup>1</sup> See this definition and definitions of a state university and of a non-public institution. It is the responsibility of the eligible institution to coordinate submissions where applications are limited. If you are uncertain about your institutional eligibility, including your status as a branch campus, center or affiliate, you must submit a question during the formal question and answer period and include a brief explanation why you believe these definitions are non-applicable.

certified mail (or overnight delivery with delivery confirmation), and the parent institution will be given five business days to respond. Failure to respond in a timely fashion will result in the rejection of all TSP Grant applications from the institution(s) in question.

- b. **One** application for an **inter-institutional** (involving more than one eligible institution contributing to the required match) TSP Grant. The submission of an inter-institutional TSP Grant application will count as the only allowable inter-institutional submission for each eligible institution collaborating on the application.

Multiple inter-institutional submissions from the same institution will result in the rejection of all inter-institutional TSP applications in which that institution is named until clarification is received regarding which application shall be the submission for this funding cycle. The Program will correspond with the parties involved in the multiple applications via certified mail (or overnight delivery with delivery confirmation), and the parent institution will be given five business days to respond. Failure to respond in a timely fashion will result in the rejection of the multiple TSP applications from the institution(s) in question. For the purposes of the Program, all affiliates of a public or private university shall be considered one and the same with that university.

2. A single institutional letter of support is required for the intra-institutional TSP Grant application. An institutional letter of support is required from all institutions involved in the inter-institutional application. Letters of support must **specifically** describe the matching funds and/or other resources, excluding indirect costs and space rental costs, which the institution will contribute to support the proposed research project. The value of institutional matching funds and/or resources must be at least 25 percent of the grant amount (for example, a match of \$250,000 is required for a grant award amount of \$1,000,000). Each collaborating institution must contribute a minimum of 25 percent of the matching requirement.
3. The proposed work must not duplicate or significantly overlap the funding of other research support for the Project Director or any participating Principal Investigator(s) or other TSP Grant applications. Overlap, whether scientific, financial, or commitment of a project member's effort greater than 100 percent, is not permitted.

### C. Required TSP Application Components

A complete application package **must** contain all required items listed in Table 3.

<b>Table 3. TSP Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
<b>General Research Information*:</b>			
A	Cover Page/Certification and General Research Information	2	Required. <b>Original signed cover page must be delivered separately by due date as specified in Chapter 11.</b>
B	Project Summary	1500 characters	Required. This section should provide a general audience project summary.
C	Scientific Abstract	2000 characters	Required. This is the scientific description of the research.
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 research is related to tobacco-related diseases.
<b>Main Application Body**:</b>			
F	Table of Contents	1	Required
G	Resources	2	Required
H	TSP Project Narrative	8	Required
I	Research Plan ( <i>page limits include text plus all figures, charts, tables and diagrams, etc.</i> ):		
	<ul style="list-style-type: none"> <li>• 11-14</li> <li>• 15</li> </ul>	40	Required
J	Literature Cited	18	
K	Human Subjects	No limit	Required if applicable
L	Vertebrate Animals	No limit	Required if applicable

<b>Table 3. TSP Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
M	Consortium/Contractual Agreements	2	Required if applicable
N	Consultants	2	Required if applicable
O	Institutional Letter(s) of Support	3	Required. A scanned copy of the original signed institutional letter(s) of support must be included in the application.
P	Biographical Sketch(es)	4 per person	Required for all key personnel.
Q	Miscellaneous letters of support	No limit	Optional
R	Publications, including accepted or submitted manuscripts	5 per Project Director and Principal Investigators	Optional
S	Survey Instruments	No limit	Optional
<b>Appendices:</b>			
I	Budget	15	Required. The budget will explain the planned spending for the proposed work.
II	Research Milestone Chart	5	Required. The Research Milestone Chart provides a high-level overview of the project schedule.
III	Other Support	No Limit	Required. This is a report of all other active and pending awards for all key personnel.

<b>Table 3. TSP Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
IV	Applicant's Institution IRB 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, IACUC, the DOH IRB and local IRB. Project work may not begin until all approvals are obtained. <u>Project name on approvals must match the application project name.</u>
V	Certification – Signed Page 1	1	Required. A pdf copy of the signed certification/cover page of the application that was mailed to DOH.
<p><b>TOTAL MAXIMUM PAGE LIMIT: 125 printed pages</b></p> <p><b>TOTAL MAXIMUM UPLOADED FILE SIZE: 6 MB</b></p> <p>Includes cover page and all required and optional sections (including Appendices). Proposals exceeding the total maximum page limits are subject to truncation to the page limit or may be disqualified without review.</p>			
<p>* (Sections A-E) 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>** (Sections F-S) 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>			

## **10. TECHNOLOGY TRANSFER/COMMERCIALIZATION PARTNERSHIP (TTCP) GRANT**

The intent of this grant mechanism is to encourage biomedical researchers at eligible Florida institutions to collaborate with established small business entities in order to fund efforts towards technology transfer and/or commercialization. One objective is to establish the technical/scientific merit and feasibility of the proposed development efforts so that the project may become competitive for further SBIR/STTR-type federal funding. However the grant may also be used to develop training materials for the dissemination of new and novel practices or treatments resulting from your research.

Although preliminary data are not required, proposals must address the feasibility of the research topic.

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

- Development of components required in an SBIR/STTR application beyond the basic research that led to an invention disclosure
- Developing/improving biomedical equipment useful in the diagnosis or treatment of tobacco-related disease(s)
- Developing/improving assays useful in the diagnosis or treatment 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. TTCP Award Amount and Duration**

1. The maximum award for a TTCP Grant is \$100,000 in total costs (including direct and indirect costs).
2. TTCP awards are for a period of 12 months and will begin on or around July 1, 2009.
3. TTCP grants are not eligible for subsequent non-competitive continuation support.

### **B. Specific TTCP Eligibility Requirements**

In addition to the global eligibility requirements discussed in Chapter 4, the following conditions must be met:

1. Previous recipients of James and Esther King Program Small Business Technology Transfer awards are only eligible to reapply for this grant mechanism for significantly different research projects. The Program shall make the determination as to whether the proposal is unique.
2. An eligible institution shall perform a minimum of 40 percent of the work, and a minimum of 30 percent of the work shall be performed by an eligible established small business entity.

3. An eligible established small business entity for the purposes of this program must have a place of business in Florida and meet 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 this state;
  - 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 17).
4. The Principal Investigator must have his/her primary employment with an eligible institution.
5. A letter of support from the eligible established small business entity must be provided. The letter should describe the relationship, role, and contribution to the proposed project that it will make; the type of business entity it is as defined in s. 606.03(1); *F.S.*, the entity's Federal Entity Identification Number (FEIN) or in lieu of that, a Dun and Bradstreet (DUNS) number; and an attestation that it meets the criteria for eligibility at the time of application.

### C. Required TTCP Application Components

A complete application package **must** contain all required items listed in Table 4.

Table 4. TTCP Grant Application Components and Page Limitations			
Section	Category	Page Limit	Comment
<b>General Research Information*:</b>			
A	Cover Page/Certification and General Research Information	2	Required. <b>Original signed cover page must be delivered separately by due date as specified in Chapter 11.</b>
B	Project Summary	1500 characters	Required. This section should provide a general audience project summary.
C	Scientific Abstract	2000 characters	Required. This is the scientific description of the research.
D	Key Personnel	1	Required. This section identifies all key personnel.

<b>Table 4. TTCP Grant Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
E	Tobacco-Relatedness	3000 characters	Required. This section should provide a clear explanation of how the proposed technology transfer effort is related to the prevention, diagnosis, treatment, or cure, of one or more tobacco-related diseases.
F	Small Business	1	Required. This section requests information regarding the small business and effort to be performed by the eligible institution and small business.
<b>Main Application Body**:</b>			
G	Table of Contents	1	Required
H	Resources	2	Required
I	Research Plan	10	Required
J	Literature Cited	6	Required
K	Human Subjects	No limit	Required if applicable
L	Vertebrate Animals	No limit	Required if applicable
M	Consortium/Contractual Agreements	7 per contract	Required if applicable
N	Consultants	2	Required if applicable
O	Small Business Letter of Support	3	Required. A scanned copy of the original signed Letter of Support must be included in the application.

<b>Table 4. TTCP Grant Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
P	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 Chapter XXXVI, Business Organizations, <i>F.S.</i> ; or in lieu of either of those above, a county business license	2	Required
Q	Biographical Sketch(es)	4 per person	Required for all key personnel, including the Mentor.
R	Miscellaneous Letters of Support	No limit	Optional
S	Publications, including accepted or submitted manuscripts	10	Optional
T	Survey Instruments	No limit	Optional
<b>Appendices:</b>			
I	Budget	4	Required. The budget will explain the planned spending for the proposed work.
II	Research Milestone Chart	2	Required. The Research Milestone Chart provides a high-level overview of the project schedule.
III	Other Support	No Limit	Required. This is a report of all other active and pending awards for all key personnel.

<b>Table 4. TTCP Grant Application Components and Page Limitations</b>			
<b>Section</b>	<b>Category</b>	<b>Page Limit</b>	<b>Comment</b>
IV	Applicant's Institution IRB 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, IACUC, the DOH IRB (if necessary) and local IRB. Project work may not begin until all approvals are obtained. <u>Project name on approvals must match the application project name.</u>
V	Certification – Signed Page 1	1	Required. A pdf copy of the signed certification/cover page of the application that was mailed to DOH.
<b>TOTAL MAXIMUM PAGE LIMIT: 75 printed pages</b> <b>TOTAL MAXIMUM UPLOADED FILE SIZE: 3 MB</b> Includes cover page and all required and optional sections (including Appendices). Proposals exceeding the total maximum page limits will be returned without review.			
<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 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>** (Sections G-T) 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>			

## 11. SCHEDULE OF IMPORTANT DATES

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

<b>Table 5. Schedule of Important Dates</b>		
<b>ACTIVITY</b>	<b>DATES</b>	<b>IMPORTANT INFORMATION</b>
Competition opens for online application	December 1, 2008	Visit <a href="http://www.floridabiomed.com">www.floridabiomed.com</a> and register for an online application.
Written questions will be accepted	<b>QUESTIONS MAY BE SUBMITTED AT ANY TIME AFTER THE CALL IS PUBLISHED AND MUST BE RECEIVED BEFORE 5:00 PM EST JANUARY 12, 2009</b>	E-mail questions to: <a href="mailto:questions@floridabiomed.com">questions@floridabiomed.com</a>
Answers will be posted to written questions	At least two updates will be made to the website during the open Call. <b>Final updates will be posted by JANUARY 23, 2009</b>	Find questions and answers at <a href="http://floridabiomed.com/king_ga.html">http://floridabiomed.com/king_ga.html</a>
Online applications are due	<b>APPLICATIONS MUST BE SUBMITTED BEFORE 5:00 PM EST FEBRUARY 13, 2009</b>	Online applications must be submitted through <a href="http://www.floridabiomed.com">www.floridabiomed.com</a>
Original signed cover / certification page is due	<b>COVER / CERTIFICATION PAGES MUST BE POSTMARKED BY FEBRUARY 13, 2009 FOR RECEIPT NO LATER THAN FEBRUARY 16, 2009</b>	Send signed cover / certification page to the Biomedical Research Program, Florida Department of Health address listed in Chapter 16 B.
Awards announced	On or around June 1, 2009	Award letters will be sent to the Sponsored Research Official and the Principal Investigator will receive notification by e-mail.

<b>Table 5. Schedule of Important Dates</b>		
<b>ACTIVITY</b>	<b>DATES</b>	<b>IMPORTANT INFORMATION</b>
Proposal evaluation summaries are available to applicants online	On or around June 1, 2009	Whether or not funding is awarded, the evaluation report will be available to the Principal Investigator by logging in at <a href="http://www.floridabiomed.com">www.floridabiomed.com</a> .
Regulatory Approvals Due (if applicable)	Immediately after award notification, grantees should submit all necessary applications to regulatory authorities including, but not limited to, IACUC, the DOH IRB, and local IRB. Project work may not begin until all approvals are obtained.	Send scanned signed approvals to: <a href="mailto:programsupport@floridabiomed.com">programsupport@floridabiomed.com</a>  Note: The project name on the approvals must match the application project name.  Refer to Chapter 17 for the DOH IRB definition to determine if approval is required for your project. Visit <a href="http://www.flpublichealthethics.net">www.flpublichealthethics.net</a> for DOH IRB instructions and forms.
Grants begin	July 1, 2009	Contingent on verification of all eligibility requirements and regulatory approvals.

Dates after the application due date are subject to change. The Program website at [www.floridabiomed.com](http://www.floridabiomed.com) will post substantive changes. Applicants should monitor the website for changes and announcements.

## **12. 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. Applicants, or persons acting on their behalf, may not contact employees of the Department of Health or members of the Biomedical Research Advisory Council regarding this Call for Applications from the time of the release of the Call until the awards are announced. The Department's contracted agent for managing the Call and applications, the Lytmos Group, may only be contacted on programmatic issues in writing via e-mail as indicated below. The only exception to this is for technical questions described in item B below. Violations of this provision may be grounds for disqualifying an application.

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](mailto:questions@floridabiomed.com) by the date and time shown in Chapter 11.

Answers to questions received before the deadline will be available on the Program website, [www.floridabiomed.com](http://www.floridabiomed.com) by the date and time at specific location indicated in Chapter 11. 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 inquiries pertaining to 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](mailto: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.

## **13. EVALUATION OF SUBMITTED 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 document.

The Program will consider the outcome of each of these evaluation steps in making final funding recommendations to the Florida State Surgeon General. Also see Chapter 2, Grant-Making Process Overview, for a flow chart of the grant process.

### **A. Administrative Review**

Each application submitted by the date and time indicated in Chapter 11 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 of the application.

Application materials not received according to the dates, times, and locations specified in Chapter 11 will be disqualified.

Any application failing to meet all administrative requirements may be ruled ineligible for funding in this competition and not entitled to further consideration. However, as a service to Florida investigators, the Program may elect to allow ineligible proposals to undergo 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**

Except for Bridge Grants, for which the results of the national peer review of the Qualifying Federal Proposal will be the primary consideration, Program peer reviewers will assess the scientific merit of all 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 carry out the work. Reviewers will be nationally prominent individuals drawn from various sectors in the life sciences field 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). Every eligible application will be assigned to three or more independent peer reviewers (three for Bridge, five for NIR and TTCP, and seven for TSP). Each reviewer will submit to Lytmos Group their ratings and comments online. 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 others. Except for Bridge Grants, the high and low scientific merit scores will be dropped and the remaining scores will be averaged to determine the overall score for scientific merit. All peer reviews will be complete by the date and time shown in Chapter 11, after which reviewers will be able to see only the final evaluation reports for the applications they evaluated.

**For Bridge Grant applications:** Peer reviewers will not re-assess the overall scientific merit of the research described in the Qualifying Federal Proposal; however, three independent scientists will evaluate each application for the following criteria:

- Feasibility of the proposed Bridge Grant research plan
- Relationship of the project to the advancement toward prevention, diagnosis, treatment, and cure of tobacco-related diseases

**For all other applications:** Peer reviewers will rate all NIR, TSP, and TTCP proposals for scientific merit for the following criteria:

- Scientific and technical quality of the proposed project or activity
- Significance, approach, and feasibility of the research plan
- Qualifications of the Principal Investigator to carry out the proposed project
- Available resources and environment
- Relationship of the project to the advancement toward prevention, diagnosis, treatment, and cure of tobacco-related diseases

- **For NIR applications:** Commitment of the institution and mentor to the development of the new investigator, qualifications of the mentor, quality of the environment conducive to the development of the new investigator, and the extent of partnering and collaboration between different institutions if proposed
- **For TSP applications:** The goals and significance of the overall project, the integral programmatic theme, evidence of coordination, interrelationships and synergy among the research projects, value of core facilities and services supporting collaborative research, evidence of strong institutional commitment, and the quality of other resources
- **For TTCP applications:** The anticipated commercial value and/or societal benefits of products, processes, methods, training materials, or services under consideration

Finally, for all proposals undergoing peer review, reviewers will identify concerns regarding:

- Research related to human subjects
- Research related to animal subjects
- The budget proposed for the work outlined

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

### **C. Programmatic Review**

The Florida Biomedical Research Advisory Council will consider the results of the Scientific Merit Review and independent reviewer opinions 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.

It is important to note that 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 disease. (See Chapter 3 for Tobacco-relatedness description.)

## **14. 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 during this interval if additional 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.

## 15. REQUESTS FOR RE-CONSIDERATION

All funding decisions of the State Surgeon General are final. After receiving the peer review scores and comments, if you wish to request a re-consideration, you must submit a written statement outlining the substantive concern and basis for such. This written statement must be submitted by e-mail to [programsupport@floridabiomed.com](mailto: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 your complaint, and when warranted by apparent deficiencies in the peer evaluation, may order a re-consideration. You will receive a written response from the Program containing the outcome of this process.

Based on your 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 taken into consideration, your application will be classified either as funded, fundable but unfunded, or unfundable. The best outcome an applicant can expect from a re-consideration is for his or her proposal to be more highly ranked as a result of a better score, placing that application in a more favorable position in the event additional funding becomes available. However, the result also could be movement down the ranking table.

## 16. INSTRUCTIONS FOR APPLICATION SUBMISSION

All applications must be prepared and submitted online through the online application process accessible from the Program's website, [www.floridabiomed.com](http://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 11 will be deemed noncompliant, and will be disqualified from the competition.**

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

The Program reserves the right to disqualify any and all applications, and conversely 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. 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 a right to inspect any public record. There are some documents and information which are exempt from the public records laws. Applicants are discouraged from submitting information considered proprietary unless it is deemed by the applicant to be essential for proper evaluation of the application. However, if you decide to include proprietary information, DO NOT put 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. 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 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.

### **B. Original Signature Page and Other Materials**

The original signed cover/certification page must be delivered to the Program according to the dates in Chapter 11. **All signatures must be in an ink color other than black (preferably blue) so that the original is easily recognized.** Applicants are responsible for obtaining proof of delivery from the chosen delivery carrier.

The original signed cover/certification page should be mailed to the following address:

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

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

For Courier/Express Delivery:  
4030 Esplanade Way  
Suite 280  
Tallahassee, FL 32399

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

Required signature pages such as mentorship plan or institutional 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 considered noncompliant and will be rejected.

Other documentation and materials such as cover letters, letters of support, journal articles, photographs, or diagrams are to be converted to electronic format and placed in the appropriate section of the online application. Peer reviewers will only have access to the online application and will not receive applications in paper format.

### C. Online Application Submission

To complete the application process:

1. Register as an applicant on <http://www.floridabiomed.com/login.html> and complete the brief project profile. This 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](http://www.floridabiomed.com) and change the assigned temporary password.
3. Complete the online application form for the appropriate grant mechanism (Bridge, NIR, TTCP, or TSP). Field level instructions are available online with the application form and in Addendum 1 and 2 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. You may include special formatting, scientific notation, pictures, and objects in these documents as you wish; however, within online application form fields such as the Project Title, Project Summary and the Scientific Abstract, use only conventional alphanumeric letters and numbers (i.e., ASCII text) with no drawings, special characters or symbols.
4. When you have completed the Word and Excel forms, 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](http://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.
5. Return to the website as often as you wish to work on the application. All required fields and sections must be completed before an application may be submitted. **Once submitted, applications cannot be returned.**

***Important: It is the responsibility of the applicant to ensure that a complete application is submitted before the date and time specified in Chapter 11. Applicants should anticipate that the volume of online activity may increase as the application deadline approaches and this may slow upload times. Your 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 your application is not recommended.***

### D. General Guidelines

1. An application should be self-contained and written with the care and thoroughness accorded manuscripts for publication. Review the application carefully to ensure that information essential for evaluation is included. The scientific and technical merit of the proposed research 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 form 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 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 by grant mechanism in Tables 1 through 4. 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 Tables 1 through 4, as applicable. Use the Table of Contents to ensure that a complete application is submitted. Appendices should be titled by the categories listed in Tables 1 through 4 and page numbered within the Microsoft Word template that is used for the application. Any appendices must be limited to material pertinent to the review process and kept to a minimum. **Appended material may not be used to circumvent the page limits for other sections of the application.**

## 17. 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 this state.

**Collaborator:** An individual involved with the Principal Investigator in the scientific development or execution of the project. These individuals would typically devote a specific percent of effort to the project and would be identified as key personnel. The collaborator may be employed by, or affiliated with, either the Grantee organization or an organization 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 organizations that are separate legal entities. In this arrangement, the Grantee contracts for the performance of a substantial and/or a significant portion of the activities to be conducted under the grant. These agreements typically involve a specific percent of effort from the consortium organization's Principal Investigator and a categorical breakdown of costs, 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 party. 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.

**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 400-1.2-06, 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, or facilities. Note: an application for DOH IRB approval (if applicable) is not required to be submitted until after your project has been awarded. Visit [www.flpublichealthethics.net](http://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 Established Small Business Entity:** Any entity with a principal site in Florida meeting 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 this state;
- 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 a net worth of not more than 5 million dollars; 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).

**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 percent 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 NIR applications, a mentor is considered a key personnel member.

**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.

**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 research project directly and in person.

**Principal Site:** The Florida facilities of an eligible institution or that of an organization collaborating on this project where at least two-thirds of the awarded effort and funds will be spent. It is the intent of the Program that research funded through the Program, including data analysis, occurs in Florida at the principal site.

**Project Director:** The one individual designated by the applicant institution to direct the overall TSP project to be supported by the grant. The Project Director must be a recognized senior investigator and is expected to define the integrating theme and to develop the approaches that will be used to accomplish the objective(s) of the proposed research program. The Project Director is responsible and accountable to applicant institution officials for the proper conduct of the project.

**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.

**Qualifying Federal Proposal:** For a Bridge Grant application, this is an investigator-initiated research application to a federal agency (such as an R type from NIH) that has received a peer review summary statement and percentile ranking of 30<sup>th</sup> or better (less) among all proposals submitted for the applicable competition or in absence of a percentile ranking an assigned score or rating of 2.0 (200) or lower on a scale of 1.0 to 5.0 (100 to 500), with 1.0 (100) representing the most favorable rating. Summary Statements and ratings provided as evidence of qualification must bear an agency-assigned date of February 15, 2008 or later (See Chapter 7 for more details).

**Small Business:** Per s. 288.703(1), *F.S.*, a "small business" means an independently owned and operated business concern that employs 200 or fewer permanent full-time employees and that, together with its affiliates, has a net worth of not more than \$5 million or any firm based in this state which has a small business Administration 8(a) certification<sup>2</sup> as applicable to sole proprietorships, the \$5 million net worth requirement shall include both personal and business investments.

---

<sup>2</sup> § 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.

## 18. 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 prior to the Application and signed cover page deadline. A letter of intent is not required. To obtain the application, you must complete the online registration as described in Chapter 6.*

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 new 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. Only the TSP Grant mechanism limits the number of applications a university may submit.*

4. Can one university collaborate with another university outside of the state of Florida for a TSP Grant?

*The Project Director and all Principal Investigators must have their primary employment at an eligible institution. The principal site for the project must be a facility located in Florida. If collaboration with an entity outside Florida is proposed, the application should explain what the collaborator brings to the research project that was not obtainable in Florida. Please also review the definition for "principal site" in Chapter 17.*

5. We are planning to submit an inter-institutional Team Science Program project that includes partners from another Florida university. May we also collaborate on an inter-institutional TSP application that a third institution will submit?

*No. One inter-institutional (involving multiple Florida institutions) TSP grant application may be submitted per institution; however, the submission counts as the only allowable inter-institutional submission for each Florida institution collaborating on the application. The following examples are offered to illustrate:*

- a. *Institution A intends to submit an inter-institutional TSP application in collaboration with Institution B. Both institutions must submit institutional letters of support (within the application) that clearly indicate how the 25 percent matching requirement is shared by each institution. Both collaborating institutions must contribute a minimum of 25 percent of the matching requirement. While each may also submit one intra-institutional (single institution) TSP application, neither may submit, nor participate as partners on, any other inter-institutional TSP applications. If Institution C also submits an inter-institutional TSP naming B as a collaborator, the Program will correspond with institutions A, B, and C via certified mail (or overnight delivery with delivery confirmation), and all three institutions will be given five business days to*

*respond. Failure to respond in a timely fashion will result in the rejection of all three inter-institutional TSP grant applications.*

- b. Institution A intends to submit an inter-institutional TSP application that involves collaboration with institutions B and C. All three institutions (A, B, & C) must submit institutional letters of support (within the application) that clearly indicate that the 25 percent matching requirement is shared among the three institutions. Each collaborating institution must contribute a minimum of 25 percent of the matching requirement. Although none of these institutions may submit, or be named as partners on, any other inter-institutional TSP application, all three institutions may still submit their own intra-institutional TSP applications.*

6. Can the Project Director or Principal Investigator on an intra-institutional TSP application also be a Project Director or Principal Investigator on an inter-institutional TSP application?

*Yes; however, scientific overlap, financial overlap, or commitment of a project member's effort greater than 100 percent is not permitted.*

7. If our TSP lists someone from another institution among our key personnel, does that automatically make it an inter-institutional TSP application?

*No; it is permissible to involve personnel from multiple institutions in an intra-institutional TSP Grant. In this case, the submitting institution is solely responsible for meeting the 25 percent matching requirement.*

8. Clarify the term “**affiliates**” as used in the Chapter 4, Global 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 11 for dates).*

9. I previously received a non-mentored career development grant with a budget over \$100,000 in direct costs. Does that affect my eligibility for an NIR Grant?

*Yes. The Principal Investigator **must not** have previously served as Principal Investigator on a non-mentored, peer-reviewed national grant with a budget of \$100,000 or more per year in direct costs, including non-mentored career development grants.*

10. Can a NIR Principal Investigator have more than one mentor (provided they will be within the total budget limit for mentors)?

*The NIR Principal Investigator may have more than one mentor. It is not recommended, but it will not affect the merit score. Each mentor must submit a mentorship plan and describe the mentoring relationship.*

11. I am a new investigator planning to submit to the NIR mechanism. I have also been invited to join a Team Science Program team. Can I submit to both mechanisms without hurting the chances for either, assuming the aims are scientifically distinct? Can my NIR mentor be a co-Principal Investigator on the TSP proposal? In addition, would the same reviewers review both grants?

*You can apply as the Principal Investigator for a NIR Grant and as a participant on a TSP proposal. You may not be the Project Director or a Principal Investigator on the TSP proposal. The NIR mentor can be a co-Principal Investigator on the TSP proposal. The grants may or may not be reviewed by the same reviewers. An individual's effort on all projects and responsibilities at the university can not exceed 100 percent. In addition, scientific and financial overlap is not permitted.*

12. If I have a James and Esther King NIR Grant that ends in 2008, am I still eligible to apply for another NIR Grant this year?

*Previous recipients of NIR awards through the James and Esther King Program are not eligible to reapply for another NIR Grant. Previous NIR recipients may apply for Bridge, TSP, and TTCP grants. There can be no scientific, financial, or commitment overlap between the active grant and the grant proposal.*

13. The Call asks that the mentorship plan in an NIR application include the percentage of the mentor's effort that will be devoted to the principal investigator. Does the mentor have to list a specific percent effort?

*Yes, the Mentor must identify how much time will be spent mentoring the Principal Investigator in the mentorship plan. The mentor's percent effort must also be included in the budget, even if no salary is requested.*

14. Can a Principal Investigator submit two separate applications for the New Investigator Research Grant mechanism?

*No, an individual Principal Investigator can submit only one application.*

15. If I am a recipient of a Bridge Grant, and I manage to get my NIH grant funded in the meantime, does the Bridge grant get terminated?

*Overlap is not allowed, therefore, the Bridge Grant would terminate the day before the NIH grant begins (even if the NIH grant award amount was reduced).*

16. I received a 19 percent score on an A2 (second revision) R01 application. Technically, this R01 cannot be re-submitted without major changes, after which it is submitted as a new grant. I do intend to submit a new version of this application to the NIH. Given these circumstances, would I be eligible for the bridge funding?

*You are eligible to apply as long as you are willing to commit to resubmitting a federal proposal directly related to research described in your Qualifying Federal Proposal before June 30, 2010.*

17. I would like to apply for the Bridge Grant. I had a grant application submitted to a federal/government supported program (American Diabetes Association) which scored high but was not funded due to budgetary constraints. Am I eligible to apply for the King Bridge Grant?

*A grant previously submitted to the American Diabetes Association does not meet the qualifying criteria because the American Diabetes Association is not a federal agency. "To be eligible, applicants must have submitted an investigator-initiated research application to a federal agency (such as an R type from NIH)."*

18. I received a 20% score on an NIH STTR application. Am I eligible for the Bridge Grant mechanism with an NIH STTR application?

*A STTR type application does not meet the qualifying criteria because STTR is not an investigator-initiated research application (such as an R type from NIH). "To be eligible, applicants must have submitted a multi-year, investigator-initiated research application to a federal agency (such as an R type from NIH)."*

19. Can Bridge Grants be awarded to investigators starting up a laboratory or initiating a new field of study for which prior funding has not been received? For example, I make my first application [for a multi-year grant] to NIH and it receives a score at the 25th percentile and is not funded. Am I eligible to apply for a Bridge Grant?"

*Assuming you meet all other eligibility requirements, yes, you would be eligible to apply for a Bridge Grant under that circumstance. You are not required to have previous funding to be eligible; however, you must meet the Bridge Grant requirements outlined in Chapter 7 and the Global Eligibility Requirements outlined in Chapter 4.*

20. I recently submitted a tobacco-related cancer proposal to the Bankhead-Coley Program. I received a high score, but my project was not selected for funding. Am I eligible to apply for a James and Esther King Bridge Grant?

*To be eligible for a Bridge Grant, an applicant must submit a Qualifying Federal Proposal. Unfunded Bankhead-Coley Program applications do not meet this definition.*

21. 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.*

22. 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 percent of his/her time on a project but only request funds for 40 percent of his/her salary. Most often these two numbers are the same.*

23. Regarding "all financial resources" in Other Support – does this include institutional support funds received in the recruitment package for the PI?

*Yes, recruitment packages are reportable as "other support."*

24. 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 behavior research proposals related to tobacco use or tobacco-related diseases are appropriate and encouraged.*

25. Can a Principal Investigator submit the same project to both the Bankhead-Coley Program and the James and Esther King Program?

*Applicants may not submit duplicate projects or 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 two completely different projects to the two programs, one to each program. The Principal Investigator must decide which program is a better fit for his/her project.*

26. 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 two different projects 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 two completely different projects.*

27. 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 research projects with the greatest potential to lead to cures for tobacco-related diseases, and recognizes that cures will require multidisciplinary research. Consequently, for purposes of this Call for Applications, tobacco-relatedness may be broadly interpreted; however, a major component of the application evaluation criteria is the strength of the case made by the applicant in the potential of the proposed research to lead to cures of tobacco-related diseases. This relationship will be judged as part of the peer review process, and may be used in the final funding recommendation. Proposed projects that do not or cannot demonstrate tobacco-relatedness will not be funded.*

28. 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?

*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 page containing certifications and the budget form. Before signing these documents you should ask the Principal Investigator to share printed copies of all information relevant to the document being signed.*

29. 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, IACUC, the DOH IRB, and local IRB. Project work may not begin until all approvals are obtained. To determine if you will need to obtain DOH IRB approval, please review the definition of DOH IRB in Chapter 17, Definitions.*

30. 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 in each category, tobacco-relatedness, and the amount of funding appropriated by the Legislature are considerations used in making award decisions.*

*There were sixteen NIR, three Bridge, two SBTT, and two TSP grants awarded in 2008. Fourteen NIR, eight Bridge, and two TSP grants were awarded in 2007. Twelve NIR, two SBTT, and three TSP applicants were awarded in 2006. Eleven NIR, two SBTT, and three TSP applicants were awarded in 2005. Thirteen NIR, two SBTT, and three TSP grants were awarded in the 2004 funding cycle.*

31. Does the Program support (1) human embryonic stem cell, (2) human adult stem cell, or (3) animal embryonic stem cell research projects?

*To date, the Program has funded projects involving human adult and animal embryonic stem cell research but has not received a fundable application involving human embryonic stem cells (hESC). The Program has historically operated in general accord with the policies and procedures employed by National Institutes of Health. Absent any state law or executive order, projects that would otherwise be eligible for federal funding under NIH guidelines, likewise would be eligible for consideration under this program. Applicants utilizing stem cells in a proposed project must clearly indicate such within their application, regardless of stem cell type. As with NIH applications, if the use of hESC were proposed only hESC obtained from the NIH Stem Cell Registry would be permitted for use. In order to ensure that Program funds are used to support only stem cell research that is scientifically sound, legal, and ethical, the researcher would have to provide the unique NIH code for each cell line when applying for funding. The registry is found at <http://stemcells.nih.gov/research/registry/>. Federal policy can be found at <http://stemcells.nih.gov/policy/defaultpage.asp>.*

## **ADDENDUM 1 – INSTRUCTIONS FOR BRIDGE GRANT APPLICATIONS**

The Detailed Instructions for the Bridge Grant Application are accessible by clicking on the link below and are also available within the online Bridge application.

[Bridge Instructions](#)

## **ADDENDUM 2 – INSTRUCTIONS FOR NIR, TSP, AND TTCP GRANT APPLICATIONS**

The Detailed Instructions for NIR, TSP, and TTCP Grant Applications are accessible by clicking on the link below and are also available within the respective online application.

[NIR, TSP, TTCP Instructions](#)