



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

**Bridge Grant
New Investigator Research Grant
Specialized Programs of Research Excellence Planning Grant
Clinical Research Planning Grant**

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



Issued: December 1, 2008

TABLE OF CONTENTS

**Bankhead-Coley Cancer Research Program
Call for Grant Applications – FY 2009-2010**

Synopsis of Major Changes.....	3
1. Introduction.....	4
2. Grant-Making Process Overview	6
3. Cancer-Relatedness.....	7
4. Global Eligibility Requirements	7
5. Allowed and Disallowed Costs	8
6. Online Application Registration	9
7. Bridge Grant.....	10
A. Bridge Grant Award Amount and Duration	11
B. Specific Bridge Grant Eligibility Requirements.....	11
C. Required Bridge Grant Application Components	12
8. New Investigator Research (NIR) Grant	14
A. NIR Award Amount and Duration	14
B. Specific NIR Eligibility Requirements.....	14
C. Required NIR Application Components.....	16
9. Specialized Program of Research Excellence Planning (PRE-SPORE) Grant	19
A. SPORE Planning Grant Award Amount and Duration	22
B. Specific SPORE Planning Grant Eligibility Requirements	22
C. Required SPORE Planning Grant Application Components.....	23
10. Clinical Research Planning (CRP) Grant	26
A. CRP Award Amount and Duration.....	27
B. Specific CRP Eligibility Requirements	27
C. Required CRP Grant Application Components.....	29
11. Schedule of Important Dates.....	31
12. Inquiries and Contacts	33
A. Programmatic Questions About This Call.....	33
B. Technical Questions about the Online Application	33
13. Evaluation of Submitted Applications	34
A. Administrative Review	34
B. Scientific Merit Review.....	34
C. Programmatic Review	36
14. Notification of Funding Decision	36
15. Requests for Re-Consideration	36
16. Instructions for Application Submission	37
A. Confidentiality of Submitted Materials	37
B. Original Signature Page and Other Materials.....	37
C. Online Application Submission.....	38
D. General Guidelines	39
17. Definitions.....	40
18. Frequently Asked Questions	43
Addendum 1 – Instructions for Bridge Grant Applications	49
Addendum 2 – Instructions for NIR, Pre-SPORE, and CRP Grant Applications	49

SYNOPSIS OF MAJOR CHANGES

For convenient reference, the following list describes the significant differences between this *Call for Grant Applications* and the *Call for Grant Applications Fiscal Year 2008-2009* previously issued by the Bankhead-Coley Cancer 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, and Chapter 10, item 5 (for CRP applications) 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 SPORE Planning Grants can be up to 36 months.
9. In Chapter 9 B, item 2, a change has been made to the number of SPORE Planning Grant applications an institution can submit. An eligible institution may submit one intra-institutional SPORE Planning Grant application and one inter-institutional SPORE Planning Grant application. SPORE Planning Grant related frequently asked questions have been added in Chapter 17.
10. In Chapter 17, several definitions have been updated or added for clarification.
11. In Chapter 18, additional frequently asked questions have been added.
12. In Addendum 1, a link to the Bridge Grant application instructions has been added to this document.
13. Addendum 2, a link to the NIR, Pre-SPORE, and CRP Grant application instructions has been added to this document.

1. INTRODUCTION

In June, 2006, the Governor and Legislature created the William B. “Bill” Bankhead, Jr., and David Coley Cancer Research Program (hereafter referred to as “the Program”). The purpose of the Program is to “advance progress towards cures for cancer through grants awarded through a peer-reviewed, competitive process.” This law also provides for an annual appropriation of \$9 million for five years to provide grants to researchers seeking cures for cancer. The legislative intent of the Program is to dramatically reduce Florida’s inordinately high cancer burden, reducing both cancer incidence and mortality, while advancing scientific endeavors in this state, making Florida a world-class leader in cancer research and treatment. The Florida Department of Health, through the Office of Public Health Research (hereafter referred to as “the Department”) administers the Program with the support of a contracting partner, the Lytmos Group. The Program also solicits recommendations and suggestions from the Biomedical Research Advisory Council consistent with Section (s.) 381.922, *Florida Statutes (F.S.)*.

The Program has three long-term goals:

- Significantly expand cancer research capacity in the State
- Improve both research and treatment through greater participation in clinical trials networks
- Reduce the impact of cancer on disparate groups

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 cancer.

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. Special Programs of Research Excellence Planning Grant (Pre-SPORE)
4. Clinical Research Planning (CRP) Grant

For technical assistance completing an application, visit the Program website www.floridabiomed.com and use the Live Help feature (registered users only) or contact Lytmos Group via e-mail at bcprogramsupport@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.

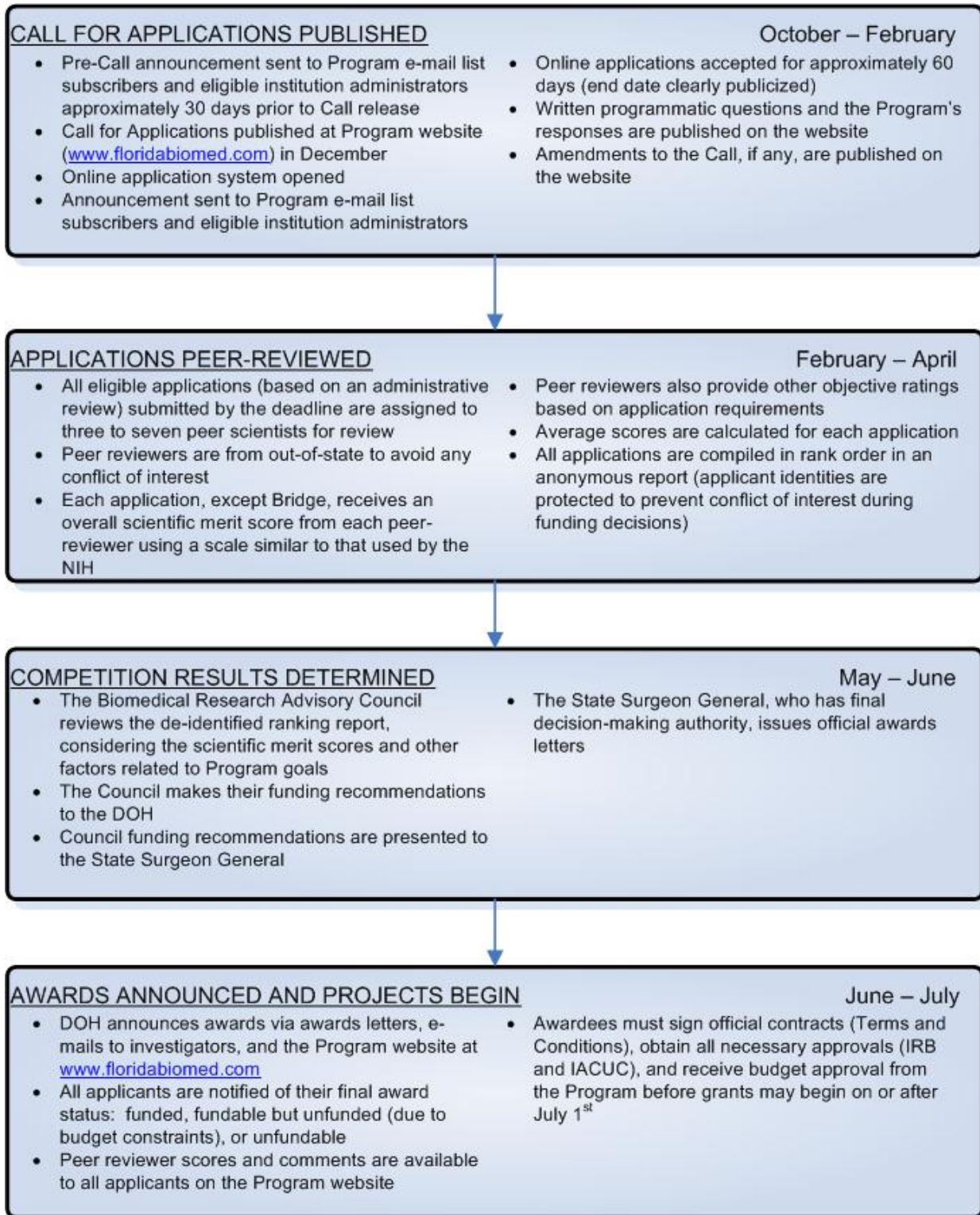
In concert with the National Institutes of Health (NIH) notice NOT-OD-08-033, Grantees shall submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available 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 for Grant Applications are subject to the availability of funds and spending authority provided by the Florida Legislature. By submitting a grant application pursuant to this Call, all applicants acknowledge and consent to this condition.

After awards are made, each grantee must sign a contract called the "Terms and Conditions," agreeing to certain legal requirements of the award. An example of the "Terms and Conditions" is located on the Program website and can be accessed by clicking on the following link: [Terms and Conditions \(www.floridabiomed.com/bc_call\)](http://www.floridabiomed.com/bc_call). The "Terms and Conditions" are non-negotiable and acceptance is required as part of the grant award process. The Program reserves the right to change or modify the "Terms and Conditions" as needed. By submitting a grant application pursuant to this Call for Applications, all applicants acknowledge this requirement.

2. GRANT-MAKING PROCESS OVERVIEW



3. CANCER-RELATEDNESS

All applicants must clearly demonstrate how the proposed research will advance progress towards cures for cancer. **Biomedical, biotechnological, and social scientific research** may involve basic science, translational or clinical research, medical devices, bioinformatics, epidemiology, or human behavior (behavioral/social scientific research). Preference may be given to grant proposals that foster collaborations among institutions, researchers, and community practitioners; as such proposals support the advancement of cures through basic or applied research, including clinical trials involving cancer patients and related networks. Proposed projects that do not or cannot demonstrate a close relationship with advancing progress toward cures for cancer or endeavor to dramatically improve cancer research and treatment 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 veterans 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.

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. 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 cost.

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 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, Pre-SPORE, or CRP). Registered applicants will receive a username and password that will allow access to the online application submission process. **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 Chapters 19 and 20 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.

7. BRIDGE GRANT

The intent of this grant mechanism is to provide interim support for promising cancer-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 (including the National Cancer Institute), the Department of Defense Congressionally Directed Medical Research Programs for Breast Cancer Research or Prostate Cancer Research, 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 R type from NIH) and have received a peer review summary statement dated on or after February 15, 2008 indicating high scientific merit (referred to elsewhere 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 30th 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 cancer 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 cures for cancer.

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: bcprogramsupport@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.

Table 1. Bridge Grant Application Components and Page Limitations			
Section	Category	Page Limit	Comment
General Research Information:			
A	Cover/Certification Page and General Research Information*	2	Required. Original signed cover page must be delivered separately by due date as specified in Chapter 11.
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**	3	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.
E	Disparate Groups	1200 characters	Required. This is a yes/no question asking if the proposed research reduces the impact of cancer on disparate group(s) and if so, how.
Appendices:			
I	Budget	4	Required. The budget will explain the planned spending for the proposed work.
II	Other Support	No Limit	Required. This is a report of all other active and pending awards for the Principal Investigator.

Table 1. Bridge Application Components and Page Limitations			
Section	Category	Page Limit	Comment
III	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 from the federal agency as indicated above.
IV	Copy of Qualifying Federal Proposal**	No Limit	Required. A pdf copy of the entire federal proposal as submitted. No additional data will be accepted.
V	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. Project name on approvals must match the application project name.
VI	Research Milestone Chart	2	Required. The Research Milestone Chart provides a high-level overview of the project schedule.
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, IV) 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 are conducted under the mentorship of a senior investigator. While all cancer-related applications are welcome, the program has a special interest in receiving biomedical, biotechnological, and social scientific research and development proposals addressing efforts to improve research and/or treatment through greater participation in clinical trial networks, and efforts to reduce the impact of cancer on disparate groups. 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 two year Bankhead-Coley Cancer Research Program Bridge Grant or a Bankhead-Coley New Investigator Research Grant are not eligible to apply for a Bankhead-Coley New Investigator Research Grant.
5. A previous recipient of a James and Esther King Biomedical Research Program New Investigator Research award may apply for a Bankhead-Coley Program 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 Bankhead-Coley 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.
11. Applicants may submit only one Bankhead-Coley 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 NIR Grant application package **must** contain all required items listed in Table 2.

Table 2. NIR Grant Application Components and Page Limitations			
Section	Category	Page Limit	Comment
General Research Information*:			
A	Cover Page/Certification and General Research Information	2	Required. Original signed cover page must be delivered separately by due date as specified in Chapter 11.
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	Cancer-Relatedness	3000 characters	Required. This section should provide a clear explanation of how the research is related to cancer.

Table 2. NIR Application Components and Page Limitations			
Section	Category	Page Limit	Comment
F	Disparate Groups	1200 characters	Required. This is a yes/no question asking if the proposed research reduces the impact of cancer on disparate group(s) and if so, how.
Main Application Body**:			
G	Table of Contents	1	Required
H	Resources	2	Required
I	Research Plan	20	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	2	Required if applicable
N	Consultants	2	Required if applicable
O	Department Head/Chair Letter of Assurance	2	Required. A scanned copy of the original signed Letter of Assurance must be included in the application.
P	Biographical Sketch(es)	4 per person	Required for all key personnel, including the Mentor.
Q	Miscellaneous Letters of Support	No limit	Optional
R	Publications, including accepted or submitted manuscripts	10	Optional
S	Survey Instruments	No limit	Optional

Table 2. NIR Application Components and Page Limitations			
Section	Category	Page Limit	Comment
Appendices:			
I	Budget	4	Required. The budget will explain the planned spending for the proposed work.
II	Other Support	No Limit	Required. This is a report of all other active and pending awards for all key personnel.
III	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 (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>
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.
V	Research Milestone Chart	4	Required. The Research Milestone Chart provides a high-level overview of the project schedule.
VI	Certification – Signed Page 1	1	Required. A pdf copy of the signed certification/cover page of the application that was mailed to DOH.
TOTAL MAXIMUM PAGE LIMIT: 75 printed pages			
TOTAL MAXIMUM UPLOADED FILE SIZE: 3 MB			
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.			

Table 2. NIR Application Components and Page Limitations

* (Sections A-F) 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 G-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.

9. SPECIALIZED PROGRAM OF RESEARCH EXCELLENCE PLANNING (PRE-SPORE) GRANT

The intent of this grant mechanism is to assemble and prepare strong interdisciplinary teams of Florida researchers to compete successfully for very large National Institutes of Health Specialized Program of Research Excellence (SPORE) grants (using the NIH P50 Specialized Center Grant mechanism) offered by the National Cancer Institute (NCI). NCI has designed its SPORE grant mechanism to improve the screening, detection, diagnosis, treatment, and prevention of organ-specific human cancers (or highly related groups of human cancers). With a requirement for translational projects involving close collaboration among investigators conducting basic and applied research, the goals of the NCI SPORE mechanism clearly align with the interests of the Bankhead-Coley Cancer Research Program.

Within a SPORE, investigators must conduct a wide spectrum of research activities, and should also contribute significantly to the development of specialized research cores and improved research model systems. The NCI uses SPORE grants to move novel ideas, which have the potential to reduce cancer occurrence and mortality and to improve survival and quality of life quickly from the basic science laboratory to the clinic. They are action-oriented. Discoveries in the basic science laboratory go to the clinic in the form of clinical trials as quickly as possible, and results in the clinic are communicated back to the basic science investigators. SPORE projects must identify the kinds of research questions that can only be accomplished through collaborations, networks, and consortia. For more information about the NCI SPORE grants, visit http://spores.nci.nih.gov/public/index_public.html.

A SPORE Planning Grant (also referred to as “Pre-SPORE”) will allow Florida institutions that have most of the separate scientific components necessary for creating a cross-disciplinary, translational research infrastructure to plan and create the organization and collaborative relationships required for an NCI SPORE. Responsive groups will include those that have a record of accomplishment performing interdisciplinary research involving basic scientists working at the cellular and molecular levels, physicians experienced in patient-oriented research, and epidemiologists experienced in studying the patterns of disease, or groups that involve extensions of existing collaborations among interdisciplinary scientists.

A SPORE Planning Grant 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 would have to contribute to the match. Institutions that do not require a planning phase are encouraged to submit directly to the NCI and not to the Bankhead-Coley Program.

Planning activities should focus on building capacity to:

- Test the relevance of biological discoveries in human cancer risk, epidemiology/genetics, prevention, early detection/screening, diagnosis, prognosis, and/or treatment
- Determine the biological bases of observations made in the clinic or population

Planning activities may take place in a single or multiple phases. For example, an application could propose a first phase to allow for formal establishment of an organizational and operational structure of the Pre-SPORE, and a second phase to provide the time and funds for the initiation of multidisciplinary development projects, development of shared cores, and for these newly-formed groups to complete recruitment efforts necessary for bringing in critical expertise.

Annual renewals of Pre-SPORE Grants will depend on the organizational and scientific progress made as the planning stage proceeds. The Program will expect Pre-SPORE awardees to compete for an NCI SPORE award within six months of the end of this award, and will require grantees to participate in a pre-application consultation with NCI program staff four to six months in advance of the SPORE submission. Successful applicants in the current solicitation may apply for SPORE funding at any point during the life of the Pre-SPORE award. If a NCI SPORE grant is received prior to the end of the Bankhead-Coley SPORE Planning Grant award period, the Bankhead-Coley SPORE Planning Grant will be terminated in good standing as of the effective date of the NCI SPORE award.

The development of necessary Pre-SPORE ingredients such as a plan for sharing data and research resources, a career development program, a developmental research program, and an intellectual property management plan are anticipated to be a part of the Pre-SPORE research efforts.

The quality and dedication of the investigators involved in the project will ultimately determine the success of the SPORE Planning Grant. Applicants must name an appropriate Project Director with expertise within the areas associated with translational research, as well as a Co-Director with expertise in a complementary basic science field. In addition, the institution must assemble a multidisciplinary leadership team of investigators who are committed to the success of the Pre-SPORE. This group of investigators will be responsible for the definition of the research goals and objectives of the Pre-SPORE, as well as ongoing activities. They must each represent a major scientific component that will be involved in the Pre-SPORE and have demonstrated scientific accomplishment, but they do not need to demonstrate prior interactive research among themselves.

During the course of the Pre-SPORE, the leadership team will be responsible for the design and implementation of planning activities that will lead to a formal framework through which scientific synergy can occur on a stable and continuing basis. This framework will consist of and should address the following elements:

1. Establishment of an organizational structure; the applicant group will define and implement a structure for a SPORE Planning team. Organizational activities must promote cross-fertilization between fields of basic and applied science relative to the designated organ-specific human cancer. Applicants must describe the types of organizational activities that will occur over the entire course of the award.
2. Establishment of core facilities necessary to support the scientific goals of the SPORE Planning project; access to equipment and resources is often a problem, especially for multidisciplinary programs. Core resources may simply be extensions of existing laboratories or facilities, or new resources essential for the development of the project. Applicants must describe the core facilities that are available and those needed for the project and justify how any requested new core facilities are unique to the institution and do not duplicate other available resources.
3. Conduct at least two translational research projects relating to an organ-specific cancer; these projects should focus on collaboration that links basic cancer biology with improved screening, detection, diagnosis, treatment, and/or prevention. Each research project must have co-directors: a basic biological scientist and an applied science researcher. Applicants must propose translational research projects, including specific aims, basic work plans, and project milestones.
4. Identification and allocation of developmental funds; up to \$50,000 of the grant may be allocated to pilot research projects. Applicants must describe the process for the selection, monitoring, funding, and, if necessary termination of development projects to be implemented.
5. Establishment of career development activities; applicants must commit to a career development program in translational cancer research and include up to \$50,000 of the grant to develop advanced post-doctoral students or clinical fellows in their last year of training or refocus careers of junior faculty or established investigators to translational research. Funds may not be used for pre-doctoral candidates or junior level post-doctoral and clinical fellows.

A. SPORE Planning Grant Award Amount and Duration

1. The maximum annual award for SPORE Planning Grants is \$500,000, 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 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 SPORE Planning Grant Eligibility Requirements

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

1. An eligible institution¹ may submit a maximum of two applications for a SPORE Planning Grant:
 - a. **One** application for an **intra-institutional** (single institution meeting the required match) SPORE Planning 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 SPORE Planning Grant 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 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 SPORE Planning 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 financial match) SPORE Planning Grant. The submission of an inter-institutional SPORE Planning 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 SPORE Planning Grant 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

¹ 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.

business days to respond. Failure to respond in a timely fashion will result in the rejection of the multiple SPORE Planning Grant applications from the institution(s) in question.

2. A single institutional letter of support is required for the intra-institutional SPORE Planning 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 on an inter-institutional Pre-SPORE 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, Co-Director, or any participating Principal Investigator or other SPORE Planning Grant applications. Overlap, whether scientific, financial, or commitment of a project member's effort greater than 100 percent, is not permitted.

C. Required SPORE Planning Grant Application Components

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

Table 3. Pre-SPORE Application Components and Page Limitations			
Section	Category	Page Limit	Comment
General Research Information*:			
A	Cover Page/Certification and General Research Information	2	Required. Original signed cover page must be delivered separately by due date as specified in Chapter 11.
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	Cancer-Relatedness	3000 characters	Required. This section should provide a clear explanation of how the research is related to cancer.

Table 3. Pre-SPORE Application Components and Page Limitations			
Section	Category	Page Limit	Comment
F	Disparate Groups	1200 characters	Required. This is a yes/no question asking if the proposed research reduces the impact of cancer on disparate group(s) and if so, how.
Main Application Body**:			
G	Table of Contents	1	Required
H	Research Plan (<i>page limits include text plus all figures, charts, tables, diagrams, etc.</i>):		
	• <i>Organizational Activities</i>	5	Required
	• <i>Core Research Facilities</i>	5	
	• <i>Translational Research Projects</i>	30	
	• <i>Developmental Projects</i>	5	
• <i>Career Development Activities</i>	5		
I	Literature Cited	6	Required
J	Human Subjects	No limit	Required if applicable
K	Vertebrate Animals	No limit	Required if applicable
L	Consortium/Contractual Agreements	2	Required if applicable
M	Consultants	2	Required if applicable
N	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.
O	Biographical Sketch(es)	4 per person	Required for all key personnel.

Table 3. Pre-SPORE Application Components and Page Limitations			
Section	Category	Page Limit	Comment
P	Survey Instruments	No limit	Optional
Appendices:			
I	Budget	15	Required. The budget will explain the planned spending for the proposed work.
II	Other Support	No Limit	Required. This is a report of all other active and pending awards for all key personnel.
III	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 (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>
IV	Research Milestone Chart	4	Required. The Research Milestone Chart provides a high-level overview of the project schedule.
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>TOTAL MAXIMUM PAGE LIMIT: 120 printed pages</p> <p>TOTAL MAXIMUM UPLOADED FILE SIZE: 5 MB</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>			

Table 3. Pre-SPORE Application Components and Page Limitations

* (Sections A-F) Submitted materials are subject to the provisions of Art. I, Sec. 24, *Florida Constitution* and Chapter 119, *Florida Statutes*, 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 G-P) If the application contains information that the applicant believes constitutes trade secrets or proprietary information or is protected by a specific statutory exemption, it should be limited to the Main Application Body. The applicant must CLEARLY identify the information with [brackets] and a footnote that specifies the law 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.

10. CLINICAL RESEARCH PLANNING (CRP) GRANT

The intent of this grant mechanism is to increase the likelihood of success in research projects involving clinical investigations (clinical trials) of new drugs, biologics, and devices intended for licensure by the Food and Drug Administration, and behavioral studies. As such, excluded from consideration would be proposals for animal research or studies involving research limited to human tissue or specimens previously collected. The grant will support complete planning, design, and documentation of clinical trials, and behavioral studies. The Clinical Research Planning Grant is designed to: 1) provide support for the development of an investigational new drug application and supporting documentation, pre-market approval for medical devices, or an investigational device exemption application and supporting documentation; or for behavioral studies, the development of a detailed study protocol and associated documents including a manual of operations; 2) support the development of other essential elements of a clinical trial or behavioral study; 3) permit early peer review of the rationale for the proposed clinical trial or behavioral study; and 4) support an optional pilot study to gather preliminary data.

Projects are conducted under the mentorship of a senior investigator with clinical investigations or behavioral research experience, as appropriate.

In the case of new drugs, biologics and devices, consistent with FDA regulations, the plan that results from this grant should include:

- the rationale for the drug or the research study
- the drug, biologic or device indication(s) to be studied
- the general approach to be followed in evaluating the drug, biologic or device
- the kinds of clinical trials to be conducted in the first year following the application
- the estimated number of patients to be given the drug, biologic or device in those studies

- a description of any risks of particular severity or seriousness anticipated on the basis of the toxicological data in animals or prior studies in humans with the drug or related drugs

Based on the results from the CRP study, it is expected that a grant recipient will apply for a full-scale national clinical trial/live human subject research grant or a follow-on Bankhead-Coley New Investigator Research Grant by the end of the CRP Grant. Otherwise a report outlining the reason for not pursuing the study must be provided.

Activities that may be supported by the CRP Grant include, but are not limited to:

- Develop an investigational new drug application for the Food and Drug Administration
- Develop a Pre-market Use of Medical Devices Application for the Food and Drug Administration
- Develop a clinical protocol
- Develop a plan for the recruitment and retention of participants
- Develop consent form(s) and, if applicable, assent form(s)
- Develop an investigator's brochure or equivalent
- Develop a manual of operations including details, validation, and quality control for any non-standard clinical or laboratory/mechanistic testing which will be performed
- Develop the data management plan
- Develop a plan for the acquisition and administration of study agents(s)

A. CRP Award Amount and Duration

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

B. Specific CRP 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 ten 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 only. The percent FTE support requested shall not exceed the actual percent of effort.

4. 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 research 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.
5. 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.
6. All applicants must have a mentoring relationship with a senior investigator with clinical investigation or behavioral research experience, as appropriate, 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.
7. All applicants must include a Department Head/Chair Letter of Assurance in their grant application.
8. Applicants may submit only one Bankhead-Coley CRP Grant application.
9. 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.
10. Clinical Research Planning Grant support is for new projects only. Continuation of previously funded national grants is not eligible.
11. Clinical investigations or behavior research must be performed in Florida.
12. IRB approvals (institution and DOH (if required)) must be obtained and provided to the Program grant manager before the pilot activities or any human subject related activities can begin.

C. Required CRP Grant Application Components

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

Table 4. CRP Application Components and Page Limitations			
Section	Category	Page Limit	Comment
General Research Information*:			
A	Cover Page/Certification and General Research Information	2	Required. Original signed cover page must be delivered separately by due date as specified in Chapter 11.
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	Cancer-Relatedness	3000 characters	Required. This section should provide a clear explanation of how the research is related to cancer.
F	Disparate Groups	1200 characters	Required. This is a yes/no question asking if the proposed research reduces the impact of cancer on disparate group(s) and if so, how.
Main Application Body**:			
G	Table of Contents	1	Required
H	Resources	1	Required
I	Research Plan	10	Required
J	Literature Cited	6	Required
K	Consortium/Contractual Agreements	2	Required if applicable
L	Consultants	2	Required if applicable

Table 4. CRP Application Components and Page Limitations			
Section	Category	Page Limit	Comment
M	Department Head/Chair Letter of Assurance	2	Required. A scanned copy of the original signed Letter of Assurance must be included in the application.
N	Biographical Sketch(es)	4 per person	Required for all key personnel, including the mentor.
O	Miscellaneous Letters of Support	No limit	Optional
P	Publications, including accepted or submitted manuscripts	10	Optional
Appendices:			
I	Budget	4	Required. The budget will explain the planned spending for the proposed work.
II	Other Support	No Limit	Required. This is a report of all other active and pending awards for all key personnel.
III	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.
IV	Research Milestone Chart	2	Required. The Research Milestone Chart provides a high-level overview of the project schedule.
V	Certification – Signed Page 1	1	Required. A pdf copy of the signed certification/cover page of the application that was mailed to DOH.
TOTAL MAXIMUM PAGE LIMIT: 60 printed pages			
TOTAL MAXIMUM UPLOADED FILE SIZE: 3 MB			
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.			

Table 4. CRP Application Components and Page Limitations

* (Sections A-F) Submitted materials are subject to the provisions of Art. I, Sec. 24, Florida Constitution and Chapter 119, Florida Statutes, 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 G-P) If the application contains information that the applicant believes constitutes trade secrets or proprietary information or is protected by a specific statutory exemption, it should be limited to the Main Application Body. The applicant must CLEARLY identify the information with [brackets] and a footnote that specifies the law 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.

11. SCHEDULE OF IMPORTANT DATES

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

Table 5. Schedule of Important Dates

ACTIVITY	DATES	IMPORTANT INFORMATION
Competition opens for online application	December 1, 2008	Visit www.floridabiomed.com and register for an online application.
Written questions will be accepted	QUESTIONS MAY BE SUBMITTED AT ANY TIME AFTER THE CALL IS PUBLISHED AND MUST BE RECEIVED BEFORE 5:00 PM EST JANUARY 12, 2009	E-mail questions to: bcquestions@floridabiomed.com

Table 5. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
Answers will be posted to written questions	At least two updates will be made to the website during the open Call. Final updates will be posted by JANUARY 23, 2009	Find questions and answers at http://floridabiomed.com/bc_qa.html
Online applications are due	APPLICATIONS MUST BE SUBMITTED BEFORE 5:00 PM EST FEBRUARY 13, 2009	Online applications must be submitted through www.floridabiomed.com .
Original signed cover / certification page is due	COVER / CERTIFICATION PAGES MUST BE POSTMARKED BY FEBRUARY 13, 2009 FOR RECEIPT NO LATER THAN FEBRUARY 16, 2009	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.
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 www.floridabiomed.com .
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 required approvals are obtained.	Send scanned signed approvals to: bcprogramsupport@floridabiomed.com 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 www.flpublichealthethics.net for DOH IRB instructions and forms.

Table 5. Schedule of Important Dates		
ACTIVITY	DATES	IMPORTANT INFORMATION
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 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 bcquestions@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 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 (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 multi-step evaluation processes 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 dates and times 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 by the Program according to the dates, times, and locations specified in Chapter 11 are subject to disqualification.

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 cancer-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 CRP, and seven for Pre-SPORE). 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 of this Call, 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 search for cures to cancer

For all other applications: Peer reviewers will rate all NIR, CRP, and Pre-SPORE 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 search for prevention, diagnoses, treatment, and cures of cancer.
- **For NIR and CRP 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 SPORE Planning Grant applications:** Level of collaboration among basic science, translational, and clinical investigators, and commitment of the institution to Pre-SPORE preparation activities

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 cancer-relatedness in a manner that is blind to the 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 that may include the relevance of the research to cancer. (See Chapter 3 for Cancer-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 Program 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 bcprogramsupport@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. 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 and use the Live Help feature or contact the Lytmos Group via e-mail at bcprogramsupport@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 specification 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 affect the interest 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 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 online 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 commitment, 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 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 and change the assigned temporary password.
3. Complete the online application form for the appropriate grant mechanism (Bridge, NIR, Pre-SPORE, or CRP). 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, all online application forms 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. 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 to 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 the 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 your application is complete. Appendices should be titled by the categories listed in Table 1 through 4, as applicable, and pages numbered. 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

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 for DOH IRB instructions and forms.

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

Established Research Institute: An established research institute eligible for Program funding is an organization that is any Florida nonprofit or foreign nonprofit covered under Chapter 617, *F.S.*, with a physical location in Florida, whose stated purpose and powers are scientific, biomedical or biotechnological research and/or development and is legally registered with the Florida Department of State, Division of Corporations. This includes federal government and non-profit medical and surgical hospitals including veterans administration hospitals.

Feasibility: The practical extent to which a project is capable of being successfully performed within the requested time and for the awarded money.

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 grant. 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 Co-Director: Each SPORE Planning Grant application must designate a Co-Director with expertise in a complementary basic science field who will work with the Project Director to direct the proposed Pre-SPORE project.

Project Director: The individual designated by the applicant institution to direct the proposed SPORE Planning project along with the Project Co-Director. The Project Director must have expertise in translational research. 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 30th 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).

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 SPORE Planning 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 SPORE Planning 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 SPORE Planning Grant project that includes partners from another Florida university. May we also collaborate on an inter-institutional SPORE Planning Grant application that a third institution will submit?

No. One inter-institutional (involving multiple Florida institutions) SPORE Planning 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 SPORE Planning Grant 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) SPORE Planning Grant application, neither may submit, nor participate as partners on, any other inter-institutional SPORE Planning Grant applications. If Institution C also submits an inter-institutional SPORE Planning Grant 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 SPORE Planning Grant 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 SPORE Planning Grant application, all three institutions may still submit their own intra-institutional SPORE Planning Grant applications.*

6. Can the Project Director or Principal Investigator on an intra-institutional SPORE Planning Grant application also be a Project Director or Principal Investigator on an inter-institutional SPORE Planning Grant 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 SPORE Planning Grant lists someone from another institution among our key personnel, does that automatically make it an inter-institutional SPORE Planning Grant application?

No; it is permissible to involve personnel from multiple institutions in an intra-institutional SPORE Planning 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 SPORE Planning Grant 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 SPORE Planning Grant 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 SPORE Planning Grant proposal. You may not be the Project Director or a Principal Investigator on the SPORE Planning Grant proposal. The NIR mentor can be a co-Principal Investigator on the SPORE Planning Grant 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 Bankhead-Coley 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 Bankhead-Coley Program are not eligible to reapply for another NIR Grant. Previous NIR recipients may apply for Bridge and SPORE Planning 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 cancer proposal to the James and Esther King Program. I received a high score, but my project was not selected for funding. Am I eligible to apply for a Bankhead-Coley Bridge Grant?

To be eligible for a Bridge Grant, an applicant must submit a Qualifying Federal Proposal. Unfunded James and Esther King 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 cancer without any biomedical component?

Refer to Chapter 3 Cancer-Relatedness, which addresses behavioral research proposals. Motivational and behavior research proposals related to cancer 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 cancer-relatedness is an absolute requirement; however, I have had several questions as to the exact interpretation of "cancer-relatedness". Is this to be understood as having "ongoing funded cancer research projects?" or does it mean "doing research that is related to cancer" or "might lead to therapies that could be used in cancer treatment" or anything in between?

The Program is interested in funding research projects with the greatest potential to lead to cures for cancer, and recognizes that cures will require multidisciplinary research. Consequently, for purposes of this Call for Applications, cancer-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 cancer cures. 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 a close relationship with advancing progress toward cures for cancer 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, cancer-relatedness, and the amount of funding appropriated by the Legislature are considerations used in making award decisions.

There were ten NIR, fifteen Bridge, and two Pre-SPORE grants awarded in 2008. Ten NIR, ten Bridge, two Special Emphasis Project (SEP), and two Pre-SPORE grants were awarded in 2007. Three NIR, twenty-three Bridge, and seven Shared Instrument (SIG) grants were awarded in 2006.

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, PRE-SPORE, AND CRP GRANT APPLICATIONS

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

[NIR, Pre-SPORE, CRP Instructions](#)